PROFESSIONAL INFORMATION FOR TELFAST® SUSPENSION

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

TELFAST® SUSPENSION, Oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL contains 6 mg fexofenadine hydrochloride.

Each 5 mL dose will provide 30 mg of fexofenadine hydrochloride.

Preservative: Potassium sorbate 0,4 % *m/m*

Contains sugar (1 g sucrose and 0,5 g xylitol per 5 mL).

Excipients with known effect:

TELFAST SUSPENSION contains 125 mg propylene glycol in each 5 mL.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

A white, uniform suspension with a raspberry cream aroma.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Seasonal allergic rhinitis

TELFAST SUSPENSION is indicated for the relief of symptoms associated with seasonal allergic rhinitis in children 2 to 11 years of age, such as sneezing, rhinorrhoea, itchy nose/palate/throat, itchy/watery/red eyes.

Chronic idiopathic urticaria

TELFAST SUSPENSION is indicated for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in children 6 months to 11 years of age.

4.2 Posology and method of administration

Posology

Seasonal Allergic Rhinitis

Children 2 to 11 years:

The recommended dose of TELFAST SUSPENSION is 30 mg (5 mL) twice daily. A dose of 30 mg (5 mL) once daily is recommended as the starting dose in paediatric patients with decreased renal function (see section 5.2).

Chronic Idiopathic Urticaria

Children 6 months to 11 years:

The recommended dose of TELFAST SUSPENSION is 30 mg (5 mL) twice daily for patients 2 to 11 years of age and 15 mg (2,5 mL) twice daily for patients 6 months to less than 2 years of age.

For paediatric patients with decreased renal function, the recommended starting doses of TELFAST SUSPENSION are 30 mg (5 mL) once daily for patients 2 to 11 years of age and 15 mg (2,5 mL), once daily for patients 6 months to less than 2 years of age (see section 5.2).

Method of administration

For oral use.

Shake bottle well, before each use.

4.3 Contraindications

Hypersensitivity to fexofenadine hydrochloride or any excipients listed in section 6.1.

4.4 Special warnings and precautions for use

There is only limited data for the use in elderly and renally or hepatically impaired adult patients. Fexofenadine hydrochloride should be administered with care in these special risk groups. The safety and efficacy of fexofenadine hydrochloride in renally or hepatically impaired children have not been established.

Sodium

TELFAST SUSPENSION contains less than 1 mmol sodium (23 mg) per 5 mL, that is to say essentially “sodium-free”.

Sucrose

TELFAST SUSPENSION contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take TELFAST SUSPENSION.

Propylene glycol

Co-administration of TELFAST SUSPENSION with any substrate for alcohol dehydrogenase such as ethanol may induce adverse effects in children less than 5 years old.

4.5 Interaction with other medicines and other forms of interaction

Erythromycin and ketoconazole

Co-administration of TELFAST SUSPENSION with either ketoconazole or erythromycin led to increased plasma concentrations of fexofenadine. Fexofenadine had no effect on the pharmacokinetics of either erythromycin or ketoconazole.

Animal studies have shown that the increase in plasma levels of fexofenadine observed after co-administration of erythromycin or ketoconazole appears to be due to an increase in gastrointestinal absorption and either a decrease in biliary excretion or gastrointestinal secretion, respectively.

Antacids

Administration of TELFAST SUSPENSION within 15 minutes of an aluminium and magnesium containing antacid decreased fexofenadine AUC by 41 % and C_{max} by 43 %. TELFAST SUSPENSION should not be taken closely in time with aluminium and magnesium containing antacids.

Fruit juices

Fruit juices such as grapefruit, orange and apple may reduce the bioavailability and exposure of fexofenadine. This is based on the results from 3 clinical studies using histamine induced skin wheals and flares coupled with population pharmacokinetic analysis. The size of wheal and flare were significantly larger when fexofenadine hydrochloride was administered with either grapefruit or orange juices compared to water. Based on the literature reports, the same effects may be extrapolated to other fruit juices such as apple juice. The clinical significance of these observations is unknown. In addition, based on the population pharmacokinetics analysis of the combined data from grapefruit and orange juices studies with the data from a bioequivalence study, the bioavailability of fexofenadine was reduced by 36 %. Therefore, to maximize the effects of fexofenadine, it is recommended that TELFAST SUSPENSION should be taken with water (see sections 4.2 and 5.2).

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of TELFAST SUSPENSION in pregnancy and lactation has not been established.

Breastfeeding

It is not known if fexofenadine is excreted in human milk. There are no adequate and well-controlled studies in women during lactation. Because many medicines are excreted in human milk, caution should be exercised when TELFAST SUSPENSION is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

On the basis of the pharmacodynamic profile and reported adverse reactions it is unlikely that TELFAST SUSPENSION will produce an effect on the ability to drive or use machines. However, patients who experience drowsiness, dizziness or fatigue should refrain from driving, engaging in potentially hazardous activities or operating machinery.

4.8 Undesirable effects

The following frequency rating has been used, where relevant:

Very common: (>1/10); common: (>1/100, ≤1/10); uncommon: (> 1/1000, ≤ 1/100); rare: (> 1/10 000, ≤ 1/1000); very rare: (≤1/10 000), including 'isolated reports'.

Side effects:

In controlled clinical trials in children aged 6 to 11 years, the most commonly reported adverse reaction considered at least possibly related to TELFAST SUSPENSION by the investigator was headache (1,0 %). The incidence of this event was similar to placebo.

Nervous system disorders:

Common: Headache

In controlled clinical trials involving paediatric patients 6 months to 5 years of age, there were no unexpected adverse events in patients treated with TELFAST SUSPENSION.

In adults, the following adverse events have been reported in clinical trials, with an incidence similar to that observed with placebo:

Nervous system disorders:

Common: Headache, drowsiness, dizziness

Gastrointestinal disorders:

Common: Nausea

General disorders and administration site conditions:

Uncommon: Fatigue

In adults, the following adverse events have been reported during controlled clinical trials with incidences less than 1 % or in post-marketing surveillance:

Immune system disorders:

Rare: Hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis.

Nervous system disorders:

Uncommon: Insomnia, nervousness, sleep disorders or paroniria

Skin and subcutaneous tissue disorders:

Rare: Rash, urticaria, pruritus

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of this medicine is important. It allows continued monitoring of the benefit/risk balance of this medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Symptoms of overdose

Dizziness, drowsiness, and dry mouth have been reported with overdoses of fexofenadine hydrochloride. Single doses of fexofenadine hydrochloride up to 800 mg (6 healthy subjects at this dose level), and doses up to 690 mg twice daily for 1 month (3 healthy subjects at this dose level) or 240 mg once daily for 1 year (234 healthy subjects at this dose level) were administered without the development of clinically significant adverse events as compared to placebo.

Treatment of overdose

Standard measures should be considered to remove any unabsorbed medicine.
Symptomatic and supportive treatment is recommended. Haemodialysis does not effectively remove fexofenadine from blood.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 5.7.1 Antihistaminics.

Pharmacotherapeutic group: Other antihistamines for systemic use, ATC code: R06AX26.

Mechanism of action

Fexofenadine hydrochloride, the major active metabolite of terfenadine, is a non-sedating antihistamine with selective peripheral H1-receptor antagonist activity.
Fexofenadine hydrochloride exhibits an antihistamine effect by 1 hour, achieves maximum effect at 2 to 3 hours, and an effect is still seen at 12 hours. There was no evidence of tolerance to these effects after 28 days of dosing.
Histamine skin wheal and flare studies in 7 to 12 year old subjects showed that following a single dose of 30 or 60 mg, antihistamine effect was observed at 1 hour and reached a maximum by 3 hours. Greater than 49 % inhibition of wheal area, and 74 % inhibition of flare area were maintained for 8 hours following the 30 and 60 mg dose.

Effects on QTc:

No statistically significant increase in mean QTc interval compared to placebo was observed in 714 subjects with seasonal allergic rhinitis given fexofenadine hydrochloride capsules in doses of 60 to 240 mg twice daily for 2 weeks. Paediatric subjects from 2 placebo-controlled trials (n=855) treated with up to 60 mg fexofenadine hydrochloride twice daily demonstrated no significant treatment- or dose-related increases in QTc. In subjects with chronic idiopathic urticaria, there were no clinically relevant differences for any ECG intervals, including QTc, between those treated with fexofenadine hydrochloride 180 mg once daily (n=163) and those treated with placebo (n=91) for 4 weeks.

5.2 Pharmacokinetic properties

The pharmacokinetics of fexofenadine hydrochloride in subjects with seasonal allergic rhinitis and subjects with chronic urticaria were similar to those in healthy subjects.

Absorption

Fexofenadine hydrochloride was rapidly absorbed following oral administration of a single dose of two 60 mg capsules to healthy male subjects with a mean time to maximum plasma concentration occurring at 2,6 hours post-dose. After administration of a single 60 mg capsule to healthy subjects, the mean maximum plasma concentration (C_{max}) was 131 ng/mL. Following single dose oral administrations of either the 60 and 180 mg tablet to healthy adult male subjects, mean C_{max} were 142 and 494 ng/mL, respectively. The tablet formulations are bioequivalent to the capsule when administered at equal doses. Fexofenadine hydrochloride pharmacokinetics are linear for oral doses up to a total daily dose of 240 mg (120 mg twice daily). The administration of the 60 mg capsule contents mixed with applesauce did not have a significant effect on the pharmacokinetics of fexofenadine in adults. Co-administration of 180 mg fexofenadine hydrochloride tablet with a high fat meal decreased the mean area under the curve (AUC) and (C_{max}) of fexofenadine by 21 and 20 % respectively.

A dose of 5 mL of TELFAST SUSPENSION containing 30 mg of fexofenadine hydrochloride is bioequivalent to a 30 mg dose of TELFAST JUNIOR tablets.

Following oral administration of a 30 mg dose of TELFAST SUSPENSION to healthy adult subjects, the mean C_{max} was 118,0 ng/mL and occurred at approximately 1,0 hour. The administration of 30 mg TELFAST SUSPENSION with a high fat meal decreased the AUC and the mean C_{max} by approximately 30 and 47 %, respectively in healthy adult subjects.

Distribution

Fexofenadine hydrochloride is 60 % to 70 % bound to plasma proteins, primarily albumin and 1-acid glycoprotein.

Biotransformation

Approximately 5 % of the total dose of fexofenadine hydrochloride was eliminated by hepatic metabolism.

Elimination

The mean elimination half-life of fexofenadine was 14,4 hours following administration of 60 mg twice daily in healthy subjects. Excretion is mainly in through the faeces with only about 10 % being excreted unchanged in the urine.

Human mass balance studies documented a recovery of approximately 80 % and 11 % of the [14C] fexofenadine hydrochloride dose in the faeces and urine, respectively. Because the absolute bioavailability of fexofenadine hydrochloride has not been established, it is unknown if the faecal component represents primarily unabsorbed medicine or the result of biliary excretion.

Special populations

Patients with renal impairment

In adult patients with mild to moderate (creatinine clearance 41-80 mL/min) and severe (creatinine clearance 11 – 40 mL/min) renal impairment, peak plasma concentrations of fexofenadine were 87 % and 111 % greater, respectively, and mean elimination half-lives were 59 % and 72 % longer, respectively, than observed in healthy subjects. Peak plasma concentrations in patients on dialysis (creatinine clearance ≤ 10 mL/min) were 82 % greater and half-life was 31 % longer than observed in healthy subjects. Based on increases in bioavailability and half-life, a dose of 60 mg once daily is recommended as the starting dose in adult patients with decreased renal function. For paediatric patients with decreased renal function, the recommended starting dose of fexofenadine is 30 mg once daily for patients 2 to 11 years of age and 15 mg once daily for patients 6 months to less than 2 years of age (see section 4.2).

Patients with hepatic impairment

The pharmacokinetics of fexofenadine in subjects with hepatic disease did not differ substantially from that observed in healthy subjects.

Elderly population

In older subjects (≥ 65 years old), peak plasma levels of fexofenadine were 99 % greater than those observed in younger subjects (< 65 years old). Mean fexofenadine elimination half-lives were similar to those observed in younger subjects.

Paediatric population

A population pharmacokinetic analysis was performed with data from 77 paediatric subjects (6 months to 12 years of age) with allergic rhinitis and 136 adult subjects. The individual apparent oral clearance estimates of fexofenadine were on average 44 % and 36 % lower in paediatric subjects 6 to 12 years (n=14) and 2 to 5 years of age (n=21), respectively, compared to adult subjects.

Administration of a 15 mg dose of fexofenadine hydrochloride to paediatric subjects 6 months to less than 2 years of age and a 30 mg dose to paediatric patients 2 to 11 years of age produced exposures comparable to those seen with a dose of 60 mg administered to adults.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Artificial raspberry cream flavour

Edetate disodium dihydrate

Poloxamer 407

Potassium sorbate

Propylene glycol

Sodium phosphate dibasic heptahydrate

Sodium phosphate monobasic monohydrate

Sucrose

Titanium dioxide

Xanthan gum

Xylitol.

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep well closed.

Shake the bottle well, before each use.

6.5 Nature and contents of container

TELFAST SUSPENSION is available in amber PET bottles with an opaque white polypropylene, child-resistant screw closure with a foam liner and induction inner seal. The bottle has a printed label and is packed in a printed outer carton. TELFAST SUSPENSION is available in the following sizes:

- 60 mL bottle containing 30 mL suspension
- 120 mL bottle containing 60 mL suspension
- 180 mL bottle containing 150 mL suspension
- 360 mL bottle containing 300 mL suspension

6.6 Special precautions for disposal and other handling

None.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Opella Healthcare South Africa (Pty) Ltd

Hertford Office Park

Building I, 4th Floor

90 Bekker Road

Midrand

1685

8. REGISTRATION NUMBER

42/5.7.1/0339

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11 February 2011

10. DATE OF REVISION OF THE TEXT

30 November 2022

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

TELFAST® SUSPENSION, 30 mg/5 mL, oral suspension

Fexofenadine hydrochloride

Contains sugar (1 g sucrose and 0,5 g xylitol per 5 mL).

Read all of this leaflet carefully because it contains important information for you

TELFAST® SUSPENSION is available without a doctor's prescription, for you or your child to treat a mild illness. Nevertheless, you or your child still need to use TELFAST® SUSPENSION carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share TELFAST® SUSPENSION with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

11. 1. What TELFAST® SUSPENSION is and what it is used for

TELFAST® SUSPENSION contains fexofenadine hydrochloride which belongs to a group of medicines called antihistamines.

TELFAST® SUSPENSION is used in children from 2 to 11 years to relieve the symptoms that occur with seasonal allergic rhinitis (hay fever) such as sneezing, runny nose, itchy nose, mouth, throat, and itchy, watery, red eyes.

TELFAST® SUSPENSION is also used in children from 6 months to 11 years to relieve symptoms of a long-term allergic skin reaction (hives) such as itchy, raised, red bumps.

12. 2. What you need to know before you take TELFAST® SUSPENSION

Do not take TELFAST® SUSPENSION:

- If you or your child are hypersensitive (allergic) to fexofenadine hydrochloride or any of the other ingredients of TELFAST® SUSPENSION (listed in section 6).

Warnings and precautions

Take special care with TELFAST® SUSPENSION:

- If you are an elderly patient.
- If you or your child have any kidney or liver problems.
- TELFAST® SUSPENSION doesn’t have notable calming effects.

Other medicines and TELFAST® SUSPENSION

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you or your child are currently taking:

- Erythromycin (used to treat a bacterial infection).
- Ketoconazole (used to treat a fungal infection).
- Antacids (used to neutralise the acid in your stomach to relieve indigestion or heartburn).

TELFAST® SUSPENSION with food and drink

You or your child should not take TELFAST® SUSPENSION with fruit juices such as grapefruit, orange or apple juice, as it may reduce the absorption and lowers the effect of TELFAST® SUSPENSION.

Pregnancy, breastfeeding and fertility

The safety of TELFAST® SUSPENSION in pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking TELFAST® SUSPENSION.

Driving and using machines

TELFAST® SUSPENSION is unlikely to affect your ability to drive a vehicle or use machines. However, if you experience sleepiness, dizziness or feeling overtired or weak, you should not drive or operate machinery.

It is not always possible to predict to what extent TELFAST® SUSPENSION may interfere with your daily activities. Do not engage in the above activities until you are aware of the measure to which TELFAST® SUSPENSION affects you.

TELFAST® SUSPENSION contains sucrose, xylitol, sodium and propylene glycol

TELFAST® SUSPENSION contains sugars (sucrose and xylitol). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TELFAST® SUSPENSION. TELFAST® SUSPENSION may be harmful to the teeth, if taken for chronic use.

TELFAST® SUSPENSION contains less than 1 mmol sodium (23 mg) per 5 mL, that is to say essentially “sodium-free”.

TELFAST® SUSPENSION contains 125 mg propylene glycol in each 5 mL. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them TELFAST® SUSPENSION, in

particular if they use other medicines that contain propylene glycol or alcohol.

13. 3. How to take TELFAST® SUSPENSION

Always take TELFAST® SUSPENSION exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Shake the bottel well, before each use.

Seasonal allergic rhinitis

Children 2 to 11 years:

- The recommended dose of TELFAST® SUSPENSION is 30 mg (5 mL) twice daily.
- A dose of 30 mg (5 mL) once daily is recommended as the starting dose in paediatric patients with decreased renal function.

Chronic idiopathic urticaria

Children 6 months to 11 years:

- The recommended dose of TELFAST® SUSPENSION is 30 mg (5 mL) twice daily for patients 2 to 11 years of age and 15 mg (2,5 mL) twice daily for patients 6 months to less than 2 years of age.
- For paediatric patients with decreased renal function, the recommended starting doses of TELFAST® SUSPENSION are 30 mg (5 mL) once daily for patients 2 to 11 years of age and 15 mg (2,5 mL), once daily for patients 6 months to less than 2 years of age.

If you take more TELFAST® SUSPENSION than you should

Symptoms of overdose may include dizziness, sleepiness and dry mouth.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take TELFAST® SUSPENSION

Take the missed dose as soon as you remember. However, if it is almost time for your next dose, continue to take the next dose at the usual time. Do not take a double dose to make up for the forgotten individual doses.

14. 4. Possible side effects

TELFAST® SUSPENSION can have side effects.

Not all side effects reported for TELFAST® SUSPENSION are included in this leaflet. Should you or your child's general health worsen or if you or your child experience any untoward effects while taking TELFAST® SUSPENSION, please consult your health care provider for advice.

If any of the following happens, stop taking TELFAST® SUSPENSION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Chest tightness, shortness of breath.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TELFAST® SUSPENSION. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache, drowsiness, dizziness.
- Nausea (feeling sick).

Less frequent side effects:

- Feeling overtired or weak (fatigue).

- Insomnia (difficulty falling or staying asleep), nervousness, sleep disorders, excess of morbid dreams and nightmares (paroniria).
- Skin rash, itching, hives.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of TELFAST® SUSPENSION.

15. 5. How to store TELFAST® SUSPENSION

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep well closed.
- Shake the bottle well, before each use.
- Do not use after the expiry date printed on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

16. 6. Contents of the pack and other information

What TELFAST® SUSPENSION contains

The active substance is fexofenadine hydrochloride.

Each 1 mL contains 6 mg fexofenadine hydrochloride.

Each 5 mL dose will provide 30 mg of fexofenadine hydrochloride.

The other ingredients are artificial raspberry cream flavour, edetate disodium dihydrate, poloxamer 407, potassium sorbate (0,4 % *m/m*) (preservative), propylene glycol, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, sucrose, titanium dioxide, xanthan gum and xylitol.

What TELFAST® SUSPENSION looks like and contents of the pack

A white to beige, uniform suspension with a raspberry cream aroma.

TELFAST® SUSPENSION is available in amber PET bottles with a purple polypropylene, child-resistant screw closure with a foam liner and induction inner seal. The bottle has a printed label and is packed in a printed outer carton. TELFAST® SUSPENSION is available in the following sizes:

- 60 mL bottle containing 30 mL suspension
- 120 mL bottle containing 60 mL suspension
- 180 mL bottle containing 150 mL suspension
- 360 mL bottle containing 300 mL suspension

Holder of Certificate of Registration:

Opella Healthcare South Africa (Pty) Ltd

4th Floor, Building I, Hertford Office Park

90 Bekker Road, Midrand, 1685

This leaflet was last revised in

20 February 2023

Registration number

42/5.7.1/0339

Date of registration

11 February 2011

For access to the professional information please follow this link:

https://pi-pil-repository.sahpra.org.za

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S1

TELFAST® SUSPENSION, 30 mg/5 mL, orale suspensie

Feksofenadienhidrochloried

Bevat suiker (1 g sukrose en 0,5 g xilitol per 5 mL).

Lees hierdie hele inligtingsblad noukeurig deur aangesien dit inligting bevat wat belangrik is vir jou.

TELFAST® SUSPENSION is beskikbaar sonder ’n doktersvoorskrif, sodat ’n geringe siekte by jou of jou kind behandel kan word. Jy of jou kind moet TELFAST® SUSPENSION nogtans versigtig gebruik om die beste resultate te verkry

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie TELFAST® SUSPENSION met enigiemand anders deel nie.
- Vra jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies benodig.

Wat is in hierdie inligtingsblad

17. 1. Wat is TELFAST® SUSPENSION en waarvoor word dit gebruik

TELFAST® SUSPENSION bevat feksofenadienhidrochloried, wat behoort aan ’n groep medisyne wat antihistamiene genoem word.

TELFAST® SUSPENSION word gebruik by kinders van 2 tot 11 jaar oud om die simptome wat voorkom met seisoenale allergiese rinitis (hooikoors) te verlig, soos nies, loopneus, neus, mond en keel wat jeuk, en oë wat jeuk, waterig en rooi is.

TELFAST® SUSPENSION word ook gebruik by kinders van 6 maande tot 11 jaar oud, om die simptome van ’n langtermyn allergiese velreaksie (korwe) soos jeukende, opgehewe rooi bulte te verlig.

18. 2. Wat jy moet weet voordat jy TELFAST® SUSPENSION neem

Moenie TELFAST® SUSPENSION neem nie:

- Indien jy of jou kind hipersensitief (allergies) is vir feksofenadienhidrochloried of enige van die ander bestanddele van TELFAST® SUSPENSION (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met TELFAST® SUSPENSION:

- Indien jy ’n bejaarde pasiënt is.
- Indien jy of jou kind enige nier- of lewerprobleme het.
- TELFAST® SUSPENSION het nie noemenswaardige kalmerende effekte nie.

Ander medisyne en TELFAST® SUSPENSION

Sê altyd vir jou gesondheidsorgverskaffer indien jy of jou kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Sê vir jou dokter of apteker indien jy of jou kind tans enige van die volgende neem:

- Eritromisien (gebruik om ’n bakteriële infeksie te behandel).
- Ketokonasool (gebruik om ’n swaminfeksie te behandel).
- Teensuurmiddels (gebruik om die suur in jou maag te neutraliseer om sodoende slegte spysvertering of sooibrand te verlig).

TELFAST® SUSPENSION met kos en drinkgoed

Jy of jou kind behoort nie TELFAST® SUSPENSION saam met vrugtesappe soos pomelo-, lemoen- of appelsap te neem nie, want dit kan TELFAST® SUSPENSION se absorpsie verminder en die uitwerking daarvan verswak.

Swangerskap, borsvoeding en vrugbaarheid

Dit is nie bepaal of TELFAST® SUSPENSION veilig is om tydens swangerskap en borsvoeding te gebruik nie.

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy TELFAST® SUSPENSION neem.

Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat TELFAST® SUSPENSION jou vermoë om ’n voertuig te bestuur of masjiene te gebruik sal affekteer. Indien jy egter slaperigheid of duiseligheid ervaar of jy voel oormoeg of swak, moet jy nie ’n voertuig bestuur of masjinerie hanteer nie.

Dit is nie altyd moontlik om te voorspel tot watter mate TELFAST® SUSPENSION mag inmeng met jou daaglikse aktiwiteite nie. Moenie bogenoemde aksies uitvoer nie, totdat jy weet tot watter mate TELFAST® SUSPENSION jou affekteer.

TELFAST® SUSPENSION bevat sukrose, xilitol, natrium en propileenglikol

TELFAST® SUSPENSION bevat suikers (sukrose en xilitol). Indien jou dokter jou ingelig het dat jy onverdraagsaam vir sekere suikers is, kontak jou dokter voordat TELFAST® SUSPENSION geneem word. Die kroniese gebruik van TELFAST® SUSPENSION mag skadelik vir tande wees

TELFAST® SUSPENSION bevat minder as 1 mmol natrium (23 mg) per 5 mL, dit is in effek

natriumvry.

TELFAST® SUSPENSION bevat 125 mg propileenglikol in elke 5 mL. Indien jou kind jonger as 5 jaar is, praat met jou dokter of apteker voordat jy vir hulle TELFAST® SUSPENSION gee, veral indien hulle ander medisynes gebruik wat propileenglikol of alkohol bevat.

19. 3. Hoe om TELFAST® SUSPENSION te neem

Neem TELFAST® SUSPENSION altyd presies soos wat in hierdie inligtingsblad aangedui word of soos wat jou dokter of apteker vir jou gesê het. Vra gerus jou dokter of apteker indien jy nie seker is nie.

Skud die bottel elke keer voor gebruik deeglik.

Seisoenale allergiese rinitis (hooikoors)

Kinders van 2 tot 11 jaar oud:

- Die aanbevole dosis TELFAST® SUSPENSION is 30 mg (5 mL) twee keer daagliks.
- ’n Dosis van 30 mg (5 mL) een keer daagliks word as aanvangsdosis by pediatriese pasiënte met verlaagde nierfunksie aanbeveel.

Chroniese idiopatiese urtikaria (korwes)

Kinders 6 maande tot 11 jaar oud:

- Die aanbevole dosis TELFAST® SUSPENSION is 30 mg (5 mL) twee keer daagliks vir pasiënte van 2 tot 11 jaar oud, en 15 mg (2,5 mL) twee keer daagliks vir pasiënte van 6 maande tot minder as 2-jarige ouderdom.
- Vir pasiënte met verlaagde nierfunksie is die aanbevole aanvangsdosisse van TELFAST® SUSPENSION 30 mg (5 mL) een keer daagliks vir pasiënte van 2 tot 11 jaar oud, en 15 mg (2,5 mL) een keer daagliks vir pasiënte van 6 maande tot minder as 2-jarige ouderdom.

Indien jy meer TELFAST® SUSPENSION neem as wat jy moet

Simptome van oordosering kan duiseligheid, slaperigheid en droë mond insluit.

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om TELFAST® SUSPENSION te neem

Neem die dosis wat jy oorgeslaan het sodra jy onthou. Indien dit egter byna tyd is vir jou volgende dosis, gaan voort om die volgende dosis op die gewone tyd te neem. Moenie ’n dubbele dosis neem om te vergoed vir die individuele dosisse wat oorgeslaan is nie.

20. 4. Moontlike newe-effekte

TELFAST® SUSPENSION kan newe-effekte hê.

Nie alle newe-effekte wat vir TELFAST® SUSPENSION gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou of jou kind se algemene gesondheid verswak of indien jy of jou kind enige ongunstige effekte ondervind terwyl TELFAST® SUSPENSION geneem word, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om TELFAST® SUSPENSION te neem en sê dadelik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik kan maak om te sluk of asem te haal.
- Bors voel benoud, kortasemheid.
- Uitslag of gejeuk.
- Floute.

Hierdie is baie ernstige newe-effekte. Indien jy daarvan ondervind, mag jy ’n ernstige allergiese reaksie op TELFAST® SUSPENSION gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- Hoofpyn, lomerigheid, duiseligheid.
- Naarheid (voel mislik).

Newe-effekte wat minder dikwels voorkom:

- Jy voel oormoeg of swak (uitputting).
- Insomnie (sukkel om aan die slaap te raak of te bly), senuweeagtigheid, slaapversteurings, oormaat morbiede drome en nagmerries (paronirie).
- Veluitslag, gejeuk, galbulte.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Rapportering van newe-effekte

Indien julle newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die vorm om ongunstige geneesmiddelreaksies te rapporteer, wat aanlyn by SAHPRA se publikasies gevind kan word:

http://www.sahpra.org.za/Publications/Index/8

Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van TELFAST® SUSPENSION te verskaf.

21. 5. Hoe om TELFAST® SUSPENSION te bêre

- Bêre alle medisynes buite bereik van kinders.
- Bêre by of onder 25 °C.
- Hou deeglik toe.
- Skud die bottel elke keer voor gebruik deeglik.
- Moenie gebruik ná die vervaldatum wat op die verpakking gedruk is nie.

- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) wegdoen nie.

22. 6. Inhoud van die verpakking en ander inligting

Wat TELFAST® SUSPENSION bevat

Die aktiewe bestanddeel is feksofenadienhidrochloried.

Elke 1 mL bevat 6 mg feksofenadienhidrochloried.

Elke dosis van 5 mL sal 30 mg feksofenadienhidrochloried verskaf.

Die ander bestanddele is kunsmatige framboosroomgeur, edetaatdinatriumdihidraat, poloksameer 407, kaliumsorbaat (0,4 % *m/m*) (preserveermiddel), propileenglikol, natriumfosfaat dibasiese heptahidraat, natriumfosfaat monobasiese monohidraat, sukrose, titaandioksied, xantaangom en xilitol.

Hoe TELFAST® SUSPENSION lyk en inhoud van die verpakking

'n Wit, eenvormige suspensie met 'n framboosroomgeur.

TELFAST® SUSPENSION is beskikbaar in amberkleurige PET-bottels met 'n pers polipropileen, kinderbestande skroefprop met 'n voering van skuim en induksie-binneseël. Die bottel het 'n bedrukte etiket en word verpak in 'n bedrukte buitenste karton. TELFAST® SUSPENSION is in die volgende groottes beskikbaar:

- 60 mL bottel wat 30 mL suspensie bevat
- 120 mL bottel wat 60 mL suspensie bevat
- 180 mL bottel wat 150 mL suspensie bevat
- 360 mL bottel wat 300 mL suspensie bevat.

Houer van die Registrasiesertifikaat:

Opella Healthcare South Africa (Edms.) Bpk.

4de Vloer, Gebou I,

Hertford Office Park

Bekkerweg 90

Midrand 1685

Hierdie voubiljet is laas hersien

20 Februarie 2023

Registrasienommer

42/5.7.1/0339

Datum van registrasie

11 Februarie 2011

Volg asseblief hierdie skakel vir toegang tot die professionele inligting:

https://pi-pil-repository.sahpra.org.za/

Professional Information for TELFAST® 120 tablets

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINAL PRODUCT

TELFAST® 120 tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains fexofenadine base 112 mg (as fexofenadine hydrochloride 120 mg).

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Peach, oblong, biconvex, film-coated tablets. One face is embossed “012”, the other face with an “e”

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TELFAST 120 is indicated in adults and children aged 12 years and over, for the relief of symptoms associated with seasonal allergic rhinitis (SAR).

4.2 Posology and method of administration

Posology

Adults and children aged 12 years and over:

One 120 mg tablet daily*:*

Special populations:

A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function (see section 4.4 and 5.2)

Paediatric population

Children under 12 years of age:

The efficacy and safety of TELFAST 120 in children under 12 has not been studied (see section 4.4).

Method of administration

Oral administration.

The film-coated tablet should not be chewed.

4.3 Contraindications

TELFAST 120 is contra-indicated in patients with known hypersensitivity to fexofenadine hydrochloride or any of its ingredients listed in section 6.1.

There is no experience with TELFAST 120 in pregnant women (see section 4.6).

TELFAST 120 should not be taken during pregnancy or by mother's breastfeeding their babies (see section 4.6).

4.4 Special warnings and precautions for use

There is only limited data for the use in elderly and renally or hepatically impaired patients.

TELFAST 120 should be administered with care in these special risk groups (see section 4.2 and 5.2).

Paediatric population

The efficacy and safety of TELFAST 120 has not been studied in children under 12 (see section 4.2).

4.5 Interaction with other medicines and other forms of interaction

TELFAST 120 does not undergo hepatic biotransformation.Co-administration of TELFAST 120 with erythromycin or ketoconazole has been found to result in a 2 - 3 times increase in the level of fexofenadine in plasma. The changes were not accompanied by any effects on the QT interval and were not associated with any increase in adverse events compared to the drugs given singly. Animal studies have shown that the increase in plasma levels of TELFAST 120 observed after co-administration of erythromycin or ketoconazole, appears to be due to an increase in gastrointestinal absorption and either a decrease in biliary excretion or gastrointestinal secretion, respectively.

No interaction between TELFAST 120 and omeprazole was observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to TELFAST 120, caused a reduction in bioavailability, most likely due to binding in the gastro-intestinal tract. It is advisable to leave 2 hours between administration of TELFAST 120 and aluminium and magnesium hydroxide containing antacids.

Paediatric population

The efficacy and safety of TELFAST 120 has not been studied in children under the age of 12 years (see section 4.2 and 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no experience with TELFAST 120 in pregnant women. TELFAST 120 should not be taken during pregnancy (see section 4.3).

Breast-feeding

TELFAST 120 should not be taken by mothers breastfeeding their babies (see section 4.3).

Fertility

No data are available

4.7 Effects on ability to drive and use machines

TELFAST 120 lacks significant sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by simultaneous intake of alcohol or other central nervous system depressants.

4.8 Undesirable effects

The following frequency rating has been used, where relevant:

Very common: (>1/10); Common: (>1/100, <1/10); Uncommon:

(> 1/1000, <1/100);

Rare: (> 1/10 000, <1/1000); Very rare: (<1/10 000), including

'isolated reports'.

In controlled clinical trials, the most frequent adverse events reported, include:

Nervous system disorders:

> 3 %: headache; 1 – 3 %: drowsiness, dizziness.

Gastrointestinal disorders:

1 – 3 % nausea

Events that have been reported during controlled trials and during post-marketing surveillance with incidences less than 1 %, include:

Nervous system disorders:

fatigue, insomnia, nervousness and sleep disorders or paroniria.

Immune system disorders:

In rare cases, rash, urticaria, pruritus and hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis have been reported.

Paediatric population

The efficacy and safety of TELFAST 120 in children under 12 has not been studied (see section 4.2 and 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of TELFAST 120 is important. It allows continued monitoring of the benefit/risk balance of TELFAST 120. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8, or to the Pharmacovigilance Unit at Sanofi at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

4.9 Overdose

Symptoms of overdose

Most reports of TELFAST 120 overdose contain limited information. However, dizziness, drowsiness and dry mouth have been reported.

Management of overdose

Standard measures should be considered to remove any unabsorbed drug. Haemodialysis does not effectively remove fexofenadine hydrochloride from blood.

Paediatric population

No data are available

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fexofenadine belongs to the medicine class A 5.7.1 Antihistamines.

Fexofenadine hydrochloride is a pharmacologically active metabolite of terfenadine and is a non-sedating, selective histamine H1-receptor antagonist. Fexofenadine exhibits an antihistaminic

effect beginning within one hour, achieving maximum effect at 6 hours and lasting 24 hours. There was no evidence of tolerance to these effects after 28 days of dosing.

Paediatric population

The efficacy and safety of TELFAST 120 in children under 12 has not been studied (see section 4.2 and 4.4).

5.2 Pharmacokinetic properties

Absorption

Fexofenadine is absorbed into the body following oral administration, with Tmax occurring at approximately 1 - 3 hours post dose. The mean Cmax value was approximately 427 ng/ml following the administration of a 120 mg dose once daily.

Distribution

Fexofenadine is 60 - 70 % plasma protein bound.

Biotransformation

Fexofenadine undergoes negligible metabolism, as it was the only major compound identified in urine and faeces of animals and man.

Elimination

The plasma concentration profiles of fexofenadine follow a bi-exponential decline, with a terminal elimination half-life ranging from 11 to 15 hours after multiple dosing. The single and multiple dose pharmacokinetics of fexofenadine are linear between 40 mg and 240 mg, taken daily.
The major route of elimination is believed to be via biliary excretion, while up to 10 % of ingested dose is excreted unchanged through the urine.

Special populations:

The elderly: (see section 4.4).

In older subjects (≥ 65 years old), peak plasma levels of fexofenadine were 99 % greater than those observed in normal volunteers (< 65 years old). Mean elimination half-lives were similar to those observed in normal volunteers.

Renally impaired: (see section 4.4).

In patients with mild (creatinine clearance 41 - 80 mL/min) to severe (creatinine clearance 11 - 40 mL/min) renal impairment, peak plasma levels of fexofenadine were 87 % and 111 % greater, respectively, and mean elimination half-lives were 59 % and 72 % longer, respectively, than observed in normal volunteers. Peak plasma levels in patients on dialysis (creatinine clearance ≤ 10 mL/min) were 82 % greater and half-life was 31 % longer than observed in normal volunteers. Based on increases of bioavailability and half-life, a dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function (see section 4.2 and 4.4).

Paediatric population

No data are available

5.3 Preclinical safety data

No data are available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Croscarmellose Sodium

Pre-gelatinised Maize Starch

Microcrystalline Cellulose

Magnesium Stearate

Film coat:

Hypromellose E-15

Hypromellose E-5

Povidone

Titanium Dioxide (E171)

Colloidal anhydrous silica

Pink Iron Oxide Blend

Yellow Iron Oxide Blend

Macrogol 400

6.2 Incompatibilities

No data are available

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a well-closed container at or below 25 °C.

KEEP OUT OF THE REACH OF CHILDREN

6.5 Nature and contents of container

Blister strips of 5, 10 or 15 tablets are packed into cartons of 10 or 30 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No data are available.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Opella Healthcare South Africa (Pty) Ltd

4th Floor, Building I, Hertford Office Park,

90 Bekker Road, Midrand, 1652

Tel. no.: 011 256 3700

8. REGISTRATION NUMBER

32/5.7.1/0446

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02 September 2008

10. DATE OF REVISION OF THE TEXT

05 October 2022

NAMIBIA Reg. No. 04/5.7.1/0386	NS1

Professionele Inligting vir TELFAST® 120 tablette

SKEDULERINGSTATUS

S1

1. NAAM VAN DIE MEDISYNE

TELFAST® 120 tablette

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

Elke filmbedekte tablet bevat feksofenadienbasis 112 mg (as feksofenadienhidrochloried 120 mg).

Suikervry.

Vir die volledige lys toevoegings, sien afdeling 6.1.

3. FARMASEUTIESE VORM

Perskekleurige, langwerpige, bikonvekse, filmbedekte tablette. Aan die een kant is die syfer “012” gedruk, aan die ander kant, ‘n “e”.

4. KLINIESE BESONDERHEDE

4.1 Terapeutiese indikasies

TELFAST 120 is aangedui vir die verligting van simptome wat verband hou met seisoenale allergiese rinitis (SAR) in volwassenes en kinders ouer as12 jaar.

4.2 Dosering en metode van aanwending

Dosering

Volwassenes en kinders 12 jaar en ouer:

Een 120 mg tablet een keer per dag.

Spesiale populasies

‘n Aanvangsdosis van 60 mg een keer per dag word aanbeveel by pasiënte met ingekorte nierfunksie (sien afdeling 4.4 en 5.2).

Pediatriese populasie

Kinders jonger as 12 jaar:

Die doeltreffendheid en veiligheid van TELFAST 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.4).

Metode van aanwending

Mondelingse toediening.

Die filmbedekte tablet moet nie gekou word nie.

4.3 Kontra-indikasies

TELFAST 120 is teenaangedui by pasiënte met ‘n geskiedenis van hipersensitiwiteit vir feksofenadienhidrochloried of enige bestanddeel daarvan, soos gelys in afdeling 6.1.

Daar is geen ondervinding in die gebruik TELFAST 120 in swanger vroue nie (sien afdeling 4.6).

TELFAST 120 moet nie tydens swangerskap of deur moeders wat hul babas borsvoed, ingeneem word nie (sien afdeling 4.6).

4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik

Daar is slegs beperkte data beskikbaar oor die gebruik by bejaarde pasiënte of pasiënte met ingekorte nier- of lewerfunksie. TELFAST 120 moet met omsigtigheid toegedien word in hierdie spesiale risikogroep (sien afdeling 4.2 en 5.2).

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2).

4.5 Interaksie met ander medikasie en ander vorms van interaksie

TELFAST 120 ondergaan nie hepatiese biotransformasie nie. Die gelyktydige toediening van TELFAST 120 met eritromisien of ketokonasool het die vlak van feksofenadien in plasma, 2-3 keer laat styg. Die veranderings het nie gepaard gegaan met enige uitwerking op die QT-interval nie en is nie geassosieer met enige toename in newe-effekte in vergelyking met dié wanneer die middels afsonderlik toegedien is nie.

Toetse op diere het getoon dat die toename in die plasmavlakke van TELFAST 120 wat na die gelyktydige toediening met eritromisien of ketokonasool waargeneem is, waarskynlik toegeskryf kan word aan verhoogde gastroïntestinale absorpsie, asook aan ’n afname in ó f galuitskeiding ó f gastroïntestinale sekresie, onderskeidelik.

Geen interaksie is tussen TELFAST 120 en omeprasool waargeneem nie. Die toediening van ‘n teensuurmiddel wat aluminium- en magnesiumhidroksied jels bevat, 15 minute voor die toediening van TELFAST 120, het egter ‘n afname in die biobeskikbaarheid tot gevolg gehad, waarskynlik toe te skryf aan binding in die gastroïntestinale kanaal. Dit is raadsaam om minstens 2 ure te laat verloop, tussen die toediening van TELFAST 120 en aluminium- en magnesiumhidroksied-bevattende teensuurmiddels.

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2 en 4.4).

4.6 Fertiliteit, swangerskap en borsvoeding

Swangerskap

Daar is geen ondervinding in die gebruik van TELFAST 120 in swanger vroue nie. TELFAST 120 moet nie tydens swangerskap gebruik word nie (sien afdeling 4.3).

Borsvoeding

TELFAST 120 moet nie deur moeders wat hul babas borsvoed, ingeneem word nie (sien afdeling 4.3).

Fertiliteit

Geen data is beskikbaar nie.

4.7 Effek op die vermoë om te bestuur en masjienerie te gebruik

TELFAST 120 het nie betekenisvolle sederende effekte nie. Pasiënte word nogtans gemaan dat ‘n klein hoeveelheid individue wél ‘n sederende effek mag ervaar. Dit is daarom raadsaam om individuele reaksie op die middel te toets, voordat ’n motor bestuur, of ingewikkelde take aangepak word. Hierdie effek mag vererger word deur die gelyktydige inname van alkohol of ander sentrale senuweesisteem depressante.

4.8 Newe-effekte

Waar van toepassing, is die volgende frekwensie-beoordeling gebruik:

Baie algemeen: (>1/10); Algemeen: (>1/100, <1/10); Ongewoon:

(> 1/1000, <1/100); Seldsaam: (> 1/10 000, <1/1000); Baie seldsaam: (<1/10 000), insluitend ‘geisoleerde gevalle’.

In gekontroleerde kliniese studies, het die mees algemene aangemelde newe-effekte die volgende ingesluit:

Senuweesisteem afwykings:

> 3 %: hoofpyn; 1 – 3 %: lomerigheid, duiseligheid.

Gastro-intestinale afwykings:

1 – 3 %: naarheid.

Gevalle met ’n insidensie van minder as 1 %, wat gedurende gekontroleerde kliniese studies en gedurende na-bemarking-waarneming aangemeld is, sluit in:

Senuweesisteem afwykings:

Moegheid, slapeloosheid, senuagtigheid en slaapstoornisse of paroniria.

Immuunsisteem afwykings:

In seldsame gevalle is uitslag, urtikarie, pruritis en hipersensitiwiteitsreaksies met manifestasies soos angio-edeem, beklemming van die borskas, dispnee, gloede en sistemiese anafilakse aangemeld.

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2 en 4.4).

Rapportering van vermoede ongunstige reaksies

Rapportering van vermoede ongustige reaksies, na die goedkeuring van TELFAST 120 is belangrik. Dit laat toe vir die voortdurende monitering van die voordeel/risiko balans van TELFAST 120. Gesondheidsdiens verskaffers word gevra om enige vermoede ongunstige reaksies aan SAHPRA te rapporteer, via die "6.04 Adverse Drug Reactions Reporting Form", wat gevind kan word onder SAHPRA se publikasies;

- **https://www.sahpra.org.za/Publications/Index/8, óf aan die**
- **Waaksaamheidseenheid van Sanofi by za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).**

4.9 Oordosering

Simptome van oordosering

Die meeste verslae oor TELFAST 120 oordosering bevat beperkte inligting. Nietemin is duiseligheid, lomerigheid en droë mond aangemeld.

Behandeling van oordosering

Standaard prosedures behoort oorweeg te word vir die verwydering van enige ongeabsorbeerde geneesmiddel. Hemodialise verwyder nie feksofenadienhidrochloried doeltreffend uit die bloed nie.

Pediatriese populasie

Geen data is beskikbaar nie.

5. FARMAKOLOGIESE EIENSKAPPE

5.1 Farmakodinamiese eienskappe

Feksofenadien behoort tot die medisyne-klas A 5.7.1 Antihistamiene.

Feksofenadienhidrochloried is ‘n farmakologies-aktiewe metaboliet van terfenadien en is ‘n nie-sederende,selektiewe histamien H_1-reseptor antagonis.

Feksofenadien toon ‘n antihistaminergiese effek binne een uur en bereik ‘n maksimum effek na 6 uur, wat 24 uur lank duur. Daar was geen bewys van toleransie teen hierde uitwerkings na 28 dae se toediening nie.

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2 en 4.4).

5.2 Farmakokinetiese eienskappe

Absorpsie

Feksofenadien word na mondelingse toediening deur die liggaam geabsorbeer en T_{maks} word ongeveer 1-3 uur na toediening bereik. Die gemiddelde K_{maks}-waarde was ongeveer 427 ng/ml na toediening van ‘n 120 mg dosis een keer per dag.

Verspreiding

Feksofenadien is 60 - 70 % plasmaproteïen gebonde.

Biotransformasie

Feksofenadien ondergaan geringe metabolisme, aangesien dit die enigste noemenswaardige produk is wat in dierlike en menslike uriene en feses voorgekom het.

Eliminasie

Die plasmakonsentrasie profiele van feksofenadien volg ‘n bi-eksponesiële afname met ‘n terminale eliminasie halfleeftyd wat wissel tussen 11 tot 15 uur na herhaalde inname. Die enkel- en meervoudige dosis farmakokinetika van feksofenadien is lineêr tussen daaglikse dossise van 40

mg en 240 mg.Die vernaamste eliminasie roete is waarskynlik galuitskeiding, terwyl tot 10 % van die dosis wat ingeneem is, onveraderd deur die uriene uitgeskei word.

Spesiale populasies

Bejaardes: (sien afdeling 4.4).

In ouer persone (≥ 65 jaar oud), was piek plasmavlakke van feksofenadien 99 % groter as dié waargeneem in normale vrywilligers (< 65 jaar oud). Gemiddelde eliminasie halfleeftye was soortgelyk as dié waargeneem in normale vrywilligers.

Renale inkorting: (sien afdeling 4.4).

In pasiënte met matige (kreatinienopruiming 41 - 80 mL/min) tot erge (kreatinienopruiming 11 - 40 mL/min) renale inkorting, was piek plasmavlakke van feksofenadien onderskeidelik 87 % en 111 % hoër, en gemiddelde eliminasie halfleeftye onderskeidelik 59 % en 72 % langer, as dié waargeneem in normale vrywilligers. Piek plasmavlakke in pasiënte op dialise (kreatinienopruiming ≤ 10 mL/min) was 82 % hoër en halfleeftyd was 31 % langer as dié waargeneem in normale vrywilligers. Gegrond op dié toename in biobeskikbaarheid en halfleeftyd, word ‘n aanvangsdosis van 60 mg een keer per dag aanbeveel vir pasiënte met ingekorte nierfunksie (sien afdeling 4.2 en 4.4).

Pediatriese populasie

Geen data is beskikbaar nie.

5.3 Pre-kliniese veiligheidsdata

Geen data is beskikbaar nie.

6. FARMASEUTIESE BESONDERHEDE

6.1 Lys van toevoegings

Tabletkern:

Natriumkroskarmellose

Pre-gegelatiniseerde mieliestysel

Mikrokristallyne sellulose

Magnesiumstereaat

Filmbedekking:

Hipromellose E-15

Hipromellose E-5

Povidoon

Titaandioksied (E171)

Kolloïdale anhidriese silika

Pienk silweroksied mengsel

Geel ysteroksied mengsel

Makrogool 400

6.2 Onverenigbaarhede

Geen data is beskikbaar nie.

6.3 Raklewe

36 maande

6.4 Spesiale voorsorgmaatreëls vir berging

Berg in ‘n digsluitende houer teen of benede 25 °C.

HOU BUITE DIE BEREIK VAN KINDERS.

6.5 Aard en inhoud van houer

Stulpverpakte stroke van 5, 10 of 15 tablette is verpak in kartonne van 10 of 30 tablette.

Nie alle pakgroottes word noodwendig bemark nie.

6.6 Spesiale voorsorgmaatreëls vir wegdoening en ander hantering

Geen data is beskikbaar nie.

7. HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

Opella Healthcare South Africa (Edms) Bpk
4de Vloer, Gebou I, Hertford Office Park,
Bekkerweg 90, Midrand, 1652

Tel. nr.: 011 256 3700

8. REGISTRASIE NOMMER(S)

32/5.7.1/0446

9. DATUM VAN EERSTE GOEDKEURING / HERNUWING VAN GOEDKEURING

02 September 2008

10. DATUM VAN HERSIENING VAN TEKS

05 Oktober 2022

NAMIBIA Reg. No. 04/5.7.1/0386	NS1

Proposed Patient Information Leaflet for TELFAST® 120 TABLETS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

TELFAST 120® Tablets

Active ingredient fexofenadine hydrochloride

Sugar free

Read all of this leaflet carefully because it contains important information for you

TELFAST 120 is available without a doctor's prescription.
Nevertheless, you will still need to use **TELFAST 120** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **TELFAST 120** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What TELFAST 120 is and what it is used for

TELFAST 120 belongs to a group of medicines called antihistamines.

TELFAST 120 is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with hay fever (seasonal allergic rhinitis) such as sneezing, runny nose and red, watery and itchy eyes.

2. What you need to know before you take TELFAST 120

Do not take TELFAST 120:

- If you are allergic to fexofenadine hydrochloride or any of the other ingredients in this medicine (listed in section 6)
- If you are pregnant or think that you may be pregnant and if you are breastfeeding your baby

Warnings and precautions

Special care should be taken with TELFAST 120:

- If you have problems with your liver or kidneys
- If you are elderly

If any of these apply to you, or if you are not sure, tell your doctor or pharmacist or healthcare provider before taking TELFAST 120

Children and adolescents

Do not use TELFAST 120 in children or adolescents below 12 years of age.

Other medicines and TELFAST 120

Tell your doctor, pharmacist, or health care provider if you are taking or have recently taken or might take any other medicines.

Indigestion medicines containing aluminium and magnesium may affect the action of **TELFAST 120** by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take **TELFAST 120** and your indigestion medicines.

Pregnancy, breastfeeding, and fertility

Ask your pharmacist or health care provider before taking any medicine.

Do not take TELFAST 120 if you are pregnant.

TELFAST 120 is not recommended during breast-feeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Driving and using machines

TELFAST 120 is unlikely to affect your ability to drive or operate machinery.

However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery. It is not always possible to predict to what extent **TELFAST 120** may interfere with the daily activities of a patient. Patients should ensure they do not engage in the above activities until they are aware of the measure to which **TELFAST 120** affects them.

3. How to take TELFAST 120

Always take **TELFAST 120** exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

Check with your doctor, pharmacist, or nurse if you are not sure.

For adults and children aged 12 years and over:

The recommended dose is one tablet (120 mg) daily. Take your tablet with water before a meal.

This medicine will start to relieve your symptoms within 1 hour and lasts for 24 hours.

If you take more TELFAST 120 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue, and dry mouth.

If you forget to take TELFAST 120

Do not take a double dose to make up for a forgotten tablet.

Take the next dose at the usual time as prescribed by your doctor, pharmacist, or healthcare provider.

If you stop taking TELFAST 120

Tell your doctor, pharmacist, or healthcare provider if you want to stop taking **TELFAST 120** before you have finished your course of treatment. If you stop taking **TELFAST 120** earlier than planned, your symptoms may return. If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

4. Possible side effects

TELFAST 120 can have side effects.

Not all side effects reported for **TELFAST 120** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **TELFAST 120**, please consult your health care provider for advice.

If any of the following happens, stop taking **TELFAST 120** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the face, lips, tongue, or throat and difficulty breathing, as these may be signs of a serious allergic reaction

These are all very serious side effects. If you have them, you may have had a serious reaction to **TELFAST 120**. You may need urgent medical attention or hospitalisation.

These are all serious side effects. You may need urgent medical attention Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache

- Drowsiness
- Nausea (feeling sick)

Less frequent side effects:

- Tiredness
- Sleepiness

Additional side effects (frequency not known)

- Difficulty sleeping (insomnia)
- Bad dreams
- Nervousness
- Diarrhoea
- Skin rash and itching
- Hives
- Serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness and difficulty breathing

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to:

SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or to the Pharmacovigilance Unit at Sanofi at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel). By reporting side effects, you can help provide more information on the safety of **TELFAST 120**.

5. How to store TELFAST 120

Store at or below 25 ºC.

KEEP OUT OF REACH OF CHILDREN.

Store in the original package.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g.toilets).

6. Contents of the pack and other information

What TELFAST 120 contains

- The active substance is fexofenadine hydrochloride. Each tablet contains 120 mg of fexofenadine hydrochloride.
- The other ingredients are: croscarmellose sodium, pre- gelatinised maize starch, microcrystalline cellulose, magnesium stearate, hypromellose E-15, hypromellose E-5, povidone, titanium dioxide (E171), colloidal anhydrous silica, pink Iron oxide blend, yellow iron oxide blend and macrogol 400.

What TELFAST 120 looks like and contents of the pack

Peach coloured, capsule-shaped, film-coated tablets. One face is embossed “012”, the other face with an “e”.

Holder of the certificate of registration:

Opella Healthcare South Africa (Pty) Ltd

4th Floor, Building I, Hertford Office Park,

90 Bekker Street, Midrand, 1652

Tel. no.: 011 256 3700

This leaflet was last revised in

Not applicable

Registration number

32/5.7.1/0446

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

TELFAST® 180 Tablets

Active ingredient fexofenadine hydrochloride

Sugar free

Read all of this leaflet carefully because it contains important information for you

TELFAST® 180 is available without a doctor's prescription.
Nevertheless, you will still need to use **TELFAST® 180** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **TELFAST® 180** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

4. What TELFAST® 180 is and what it is used for

TELFAST® 180 belongs to a group of medicines called antihistamines.

TELFAST® 180 is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling, rashes and hay fever.

TELFAST® 180 is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with hay fever (seasonal allergic rhinitis) such as sneezing, runny nose and red, watery

and itchy eyes where TELFAST® 120 has been insufficient to control the symptoms.

5. What you need to know before you take TELFAST® 180

Do not take TELFAST® 180:

- If you are allergic to fexofenadine hydrochloride or any of the other ingredients in this medicine (listed in section 6)
- If you are pregnant or think that you may be pregnant and if you are breastfeeding your baby
-

Warnings and precautions

Special care should be taken with TELFAST® 180:

- If you have problems with your liver or kidneys
- If you are elderly

If any of these apply to you, or if you are not sure, tell your doctor or pharmacist or healthcare provider before taking TELFAST® 180

Children and adolescents

Do not use TELFAST® 180 in children or adolescents below 12 years of age.

Other medicines and TELFAST® 180

Tell your doctor, pharmacist, or health care provider if you are taking or have recently taken or might take any other medicines.

Indigestion medicines containing aluminium and magnesium may affect the action of **TELFAST® 180** by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take **TELFAST® 180** and your indigestion medicines.

Pregnancy, breastfeeding, and fertility

Ask your pharmacist or health care provider before taking any medicine.

Do not take TELFAST® 180 if you are pregnant.

TELFAST® 180 is not recommended during breast-feeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Driving and using machines

TELFAST® 180 is unlikely to affect your ability to drive or operate machinery.

However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery. It is not always possible to predict to what extent **TELFAST® 180** may interfere with the daily activities of a patient. Patients should ensure they do not engage in the above activities until they are aware of the measure to which **TELFAST® 180** affects them.

6. How to take TELFAST® 180

Always take **TELFAST® 180** exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

Check with your doctor, pharmacist, or nurse if you are not sure.

For adults and children aged 12 years and over:

The recommended dose is one tablet (180 mg) daily. Take your tablet with water before a meal.

This medicine will start to relieve your symptoms within 1 hour and lasts for 24 hours.

If you take more TELFAST® 180 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue, and dry mouth.

If you forget to take TELFAST® 180

Do not take a double dose to make up for a forgotten tablet.

Take the next dose at the usual time as prescribed by your doctor, pharmacist, or healthcare

provider.

If you stop taking TELFAST® 180

Tell your doctor, pharmacist, or healthcare provider if you want to stop taking **TELFAST® 180** before you have finished your course of treatment. If you stop taking **TELFAST® 180** earlier than planned, your symptoms may return. If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

4. Possible side effects

TELFAST® 180 can have side effects.

Not all side effects reported for **TELFAST® 180** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **TELFAST® 180**, please consult your health care provider for advice.

If any of the following happens, stop taking **TELFAST® 180** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the face, lips, tongue, or throat and difficulty breathing, as these may be signs of a serious allergic reaction

These are all very serious side effects. If you have them, you may have had a serious reaction to **TELFAST® 180**. You may need urgent medical attention or hospitalisation.

These are all serious side effects. You may need urgent medical attention Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Drowsiness
- Nausea (feeling sick)

Less frequent side effects:

- Tiredness

- Sleepiness

Additional side effects (frequency not known)

- Difficulty sleeping (insomnia)
- Bad dreams
- Nervousness
- Diarrhoea
- Skin rash and itching
- Hives
- Serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness and difficulty breathing

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to: SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or to the Pharmacovigilance Unit at Sanofi at za.CHCdrugsafety@sanofi.com (email) or 011 256 3700 (tel). By reporting side effects, you can help provide more information on the safety of **TELFAST® 180**.

5. How to store TELFAST® 180

Store at or below 25 ºC.

Store in the original package.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g.toilets).

6. Contents of the pack and other information

What TELFAST® 180 contains

- The active substance is fexofenadine hydrochloride. Each tablet contains 180 mg of

fexofenadine hydrochloride.

- The other ingredients are: colloidal anhydrous silica, croscarmellose sodium, hypromellose, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch, povidone, titanium dioxide, pink and yellow iron oxide.

What TELFAST® 180 looks like and contents of the pack

Peach coloured, capsule-shaped, film-coated tablets. One face is debossed “018”, the other face with an “e”. Diameter approximately 7,6 mm x 17,3 mm. Thickness: approximately 5,3 mm.

Holder of the certificate of registration:

Opella Healthcare South Africa (Pty) Ltd

4th Floor, Building I, Hertford Office Park,

90 Bekker Street, Midrand, 1652

This leaflet was last revised in

11 May 2022

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32/5.7.1/0447

For access to the professional information please follow this link:

https://pi-pil-repository.sahpra.org.za/

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS

S1

TELFAST® 180®Tablette

Aktiewe bestanddeel: feksofenadienhidrochloried

Suikervry.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou

TELFAST® 180 is beskikbaar sonder ’n dokter se voorskrif.

Jy moet TELFAST® 180 nogtans versigtig gebruik om die beste resultate daarmee te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees om dit later weer te lees.
- Moenie TELFAST® 180 met iemand anders deel nie.
- Indien jy enige verdere inligting nodig het, vra asseblief jou gesondheidsorgverskaffer of apteker.

Wat is in hierdie inligtingsblad

1. Wat is TELFAST® 180 en waarvoor word dit gebruik

TELFAST® 180 behoort aan ’n groep medisynes genaamd antihistamiene.

TELFAST® 180 word gebruik by volwassenes en adolessente van 12 jaar en ouer om die simptome te verlig wat met langtermyn allergiese velreaksies (chroniese idiopatiese urtikaria)

voorkom, soos jeuk, swelling, uitslag en hooikoors.

TELFAST® 180 word gebruik by volwassenes en adolessente van 12 jaar en ouer om die simptome te verlig wat voorkom met hooikoors (seisoenale allergiese rinitis) soos nies, loopneus en rooi, waterige en jeukende oë, wanneer TELFAST® 120 onvoldoende was om die simptome te beheer.

2. Wat jy moet weet voordat jy TELFAST® 180 neem

Moenie TELFAST® 180 neem nie:

- Indien jy allergies is vir feksofenadienhidrochloried of vir enige van die ander bestanddele in hierdie medisyne (gelys by afdeling 6).
- Indien jy swanger is of vermoed dat jy swanger mag wees en indien jy jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met TELFAST® 180:

- Indien jy probleme met jou lewer of niere het.
- Indien jy ’n bejaarde persoon is.

Indien enige hiervan op jou van toepassing is, of as jy nie seker is nie, sê vir jou dokter, apteker of gesondheidsorgverskaffer voordat jy TELFAST® 180 neem.

Kinders en adolessente

Moenie TELFAST® 180 by kinders en adolessente jonger as 12 jaar gebruik nie.

Ander medisynes en TELFAST® 180

Sê vir jou dokter, apteker of gesondheidsorgverskaffer indien jy enige ander medisynes neem, geneem het of van plan is om te neem.

Medisynes vir slegte spysvertering wat aluminium en magnesium bevat, kan die werking van TELFAST® 180 beïnvloed deur die hoeveelheid van die medisyne wat geabsorbeer word te verminder.

Dit word aanbeveel dat jy ten minste 2 uur laat verloop tussen die tye wat jy TELFAST® 180 en jou indigestiemedisyne neem.

Swangerskap, borsvoeding en vrugbaarheid

Vra jou apteker of gesondheidsorgverskaffer voordat jy enige medisyne neem.

Moenie TELFAST® 180 neem indien jy swanger is nie.

TELFAST® 180 word nie aanbeveel wanneer jy borsvoed nie.

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy hierdie medisyne neem.

Bestuur en gebruik van masjiene

Dit is onwaarskynlik dat TELFAST® 180 jou vermoë om ’n voertuig te bestuur of masjinerie te hanteer sal belemmer.

Jy moet seker maak dat hierdie tablette jou nie slaperig of duiselig laat voel nie, voordat jy ’n voertuig bestuur of masjinerie hanteer. Dit is nie altyd moontlik om te voorspel tot watter mate TELFAST® 180 met jou daaglikse aktiwiteite mag inmeng nie. Verseker asseblief dat jy nie bogenoemde aktiwiteite uitvoer nie, totdat jy weet tot watter mate TELFAST® 180 jou affekteer.

3. Hoe om TELFAST® 180 te neem

Neem TELFAST® 180 altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter, apteker of verpleegkundige vir jou gesê het.

Vra gerus jou dokter, apteker of verpleegkundige indien jy onseker is.

Vir volwassenes en kinders van 12 jaar en ouer:

Die aanbevole dosis is een tablet (180 mg) daagliks. Neem jou tablet voor ete met water. Hierdie medisyne sal binne 1 uur begin om jou simptome te verlig en die effek duur 24 uur.

Indien jy meer TELFAST® 180 neem as wat jy behoort te neem

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Simptome van ’n oordosis by volwassenes is duiseligheid, lomerigheid, moegheid en droë mond.

Indien jy vergeet om TELFAST® 180 te neem

Moenie ’n dubbele dosis neem om te vergoed vir ’n tablet wat oorgeslaan is nie.

Neem die volgende dosis op die gebruiklike tyd wat deur jou dokter, apteker of gesondheidsorgverskaffer voorgeskryf is.

Indien jy ophou om TELFAST® 180 te neem

Sê vir jou dokter, apteker of gesondheidsorgverskaffer indien jy wil ophou om TELFAST® 180 te neem voordat jy ’n kursus van die behandeling voltooi het. Indien jy vroeër as wat beplan is ophou om TELFAST® 180 te neem, kan jou simptome terugkeer. Indien jy enige verdere vrae rakende die gebruik van hierdie medisyne het, raadpleeg jou dokter of apteker.

4. Moontlike newe-effekte

TELFAST® 180 kan newe-effekte hê.

Nie alle newe-effekte wat vir TELFAST® 180 gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid sou verswak of indien jy enige ongunstige effekte ondervind terwyl jy TELFAST® 180 neem, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg.

Indien enige van die volgende voorkom, hou op om TELFAST® 180 te neem en sê onmiddellik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal:

- Swelling van die gesig, lippe, tong of keel en moeisame asemhaling, want dit kan tekens van ’n ernstige allergiese reaksie wees.

Hierdie is baie ernstige newe-effekte. Indien jy enige daarvan ondervind, mag jy ’n ernstige reaksie op TELFAST® 180 gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Hierdie is ernstige newe-effekte. Jy mag dringend mediese sorg benodig. Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- Hoofpyn

- Lomerigheid
- Naarheid (voel mislik)

Newe-effekte wat minder dikwels voorkom:

- Moegheid
- Slaperigheid

Bykomende newe-effekte (frekwensie onbekend)

- Sukkel om te slaap (insomnia)
- Slegte drome
- Senuweeagtigheid
- Diarree
- Veluitslag en gejeuk
- Galbulte
- Ernstige allergiese reaksie wat swelling van die gesig, lippe, tong of keel, blosende gelaat, benoude bors en moeisame asemhaling kan veroorsaak.

Rapportering van newe-effekte

Indien jy enige newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegkundige.

Jy kan ook newe-effekte rapporteer aan SAHPRA via die "**6.04 Vorm vir Rapportering van Ongunstige Geneesmiddelreaksies**", wat aanlyn beskikbaar is onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8, of aan Sanofi se Eenheid vir Farmakowaaksaamheid deur 'n e-pos na za.CHCdrugsafety@sanofi.com te stuur of 011 256 3700 te skakel. Deur newe-effekte te rapporteer, kan jy help om meer inligting rakende die veiligheid van TELFAST® 180 te verskaf.

5. Hoe om TELFAST® 180 te berg

Bêre by of onder 25 °C.

Bêre in die oorspronklike verpakking.

Moenie gebruik ná die vervaldatum wat op die karton voorkom nie.

Neem alle ongebruikte medisyne na jou apteker terug.

Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) wegdoen nie.

6. Inhoud van die verpakking en ander inligting

Wat TELFAST® 180 bevat

- Die aktiewe bestanddeel is feksofenadienhidrochloried. Elke tablet bevat 180 mg feksofenadienhidrochloried.
- Die ander bestanddele is: kolloïdale anhidriese silika, natriumkruiskarmellose, hipromellose, makrogol, magnesiumstearaat, mikrokristallyne sellulose, voorafgegelatineerde mieliestysel, povidoon, titaandioksied, pienk en geel ysteroksied.

Hoe TELFAST® 180 lyk en inhoud van die verpakking

Perskekleurige, kapsulevormige, filmbedekte tablette. Aan die een kant is “018” en aan die ander kant ’n “e” ingepers. Deursnee: ongeveer 7,6 mm x 17,3 mm. Dikte: ongeveer 5,3 mm.

Houer van die registrasiesertifikaat:

Opella Healthcare South Africa (Edms.) Bpk.

4de Vloer, Gebou I, Hertford Office Park

Bekkerweg 90, Midrand, 1652

Tel. no.: 011 256 3700

Hierdie inligtingsblad is laas hersien op

11 Mei 2022

Registrasienommer

32/5.7.1/0447

Volg asseblief hierdie skakel vir toegang tot die professionele inligting:

https://pi-pil-repository.sahpra.org.za/

Professional Information for TELFAST® 180

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

TELFAST® 180 tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains fexofenadine base 168 mg (as fexofenadine hydrochloride 180 mg) per tablet.

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.

Peach, capsule-shaped, film-coated tablets. One face is embossed “018”, the other face with an “e”.

Diameter approximately 7,6 mm x 17,3 mm.

Thickness: approximately 5,3 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TELFAST® 180 is indicated in adults and children aged 12 years and over, for the relief of symptoms associated with chronic idiopathic urticaria (CIU).

TELFAST® 180 is indicated in adults and children aged 12 years and over, for the relief of symptoms associated with seasonal allergic rhinitis (SAR), where TELFAST® 120 has been insufficient to control the symptoms.

4.2 Posology and method of administration

Posology

Adults and children aged 12 years and over:

One 180 mg tablet daily.

Special populations

There is only limited data for the use in elderly and renally or hepatically impaired patients. TELFAST® 180 should be administered with care in these special risk groups. (see section 4.4 and 5.2).

Patients with a history of or ongoing cardiovascular disease should be warned that, antihistamines as a medicine class have been associated with the adverse reactions, tachycardia and palpitations (see section 4.4, 4.8 and 5.2).

Paediatric population

The efficacy and safety of TELFAST® 180 has not been studied in children under 12 (see section 4.4).

Method of administration

Oral administration.

The film-coated tablet should not be chewed.

4.3 Contraindications

TELFAST® 180 is contraindicated in patients with known hypersensitivity to fexofenadine hydrochloride or any of its inactive ingredients (see section 6.1).

There is no experience with TELFAST® 180 in pregnant women. TELFAST® 180 should not be taken during pregnancy or by mothers breastfeeding their babies (see section 4.6).

4.4 Special warnings and precautions for use

There is only limited data for the use in elderly and renally or hepatically impaired patients. TELFAST® 180 should be administered with care in these special risk groups (see section 4.2 and 5.2).

Patients with a history of or ongoing cardiovascular disease should be warned that, antihistamines as a medicine class have been associated with the adverse reactions, tachycardia and palpitations (see section 4.2, 4.8 and 5.2).

Paediatric population

The efficacy and safety of TELFAST® 180 has not been studied in children under 12 (see section 4.2).

4.5 Interaction with other medicines and other forms of interaction

Fexofenadine does not undergo hepatic biotransformation.

Coadministration of TELFAST® 180 with erythromycin or ketoconazole has been found to result in 2 - 3 times increase in the level of fexofenadine in plasma. The changes were not accompanied by any effects on the QT interval and were not associated with any increase in adverse events compared to the medicines given singly.

Animal studies have shown that the increase in plasma levels of fexofenadine observed after coadministration of erythromycin or ketoconazole, appears to be due to an increase in gastrointestinal absorption and either a decrease in biliary excretion or gastrointestinal secretion, respectively.

No interaction between [fexofenadine] TELFAST® 180 and omeprazole was observed. However, the administration of an antacid containing aluminium and magnesium hydroxide gels 15 minutes prior to TELFAST® 180 caused a reduction in bioavailability, most likely due to binding in the gastrointestinal tract. It is advisable to leave 2 hours between administration of TELFAST® 180 and aluminium and magnesium hydroxide containing antacids.

Paediatric population

The efficacy and safety of TELFAST® 180 has not been studied in children under the age of 12 years (see section 4.2 and 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no experience with TELFAST® 180 in pregnant women. TELFAST® 180 should not be taken during pregnancy (see section 4.3).

Breastfeeding

There is no experience with TELFAST® 180 in pregnant women. TELFAST® 180 should not be taken by mothers breastfeeding their babies (see section 4.3).

Fertility

No data are available.

4.7 Effects on ability to drive and use machines

Fexofenadine lacks sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by simultaneous intake of alcohol or other central nervous system depressants

4.8 Undesirable effects

The following frequency rating has been used, where relevant:

Very common (>1/10); common (>1/100, <1/10); uncommon (> 1/1 000, <1/100); rare (> 1/10 000, <1/1 000); very rare (<1/10 000), including 'isolated reports'.

Nervous system disorders:

Common: Headache, drowsiness, dizziness.

Gastrointestinal disorders:

Common: Nausea.

General disorders and administration site conditions:

Uncommon: Fatigue.

Immune system disorders:

Uncommon: Hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis.

Psychiatric disorders:

Uncommon: Insomnia, nervousness and sleep disorders.

Nervous system disorders:

Uncommon: Paroniria.

Skin and subcutaneous tissue disorders:

Uncommon: Rash, urticaria, pruritus.

In adults, the following adverse reactions have been reported in post-marketing surveillance. The frequency with which they occur is not known (cannot be estimated from available data):

Uncommon: Cardiac disorders

Tachycardia, palpitations

Paediatric population

The efficacy and safety of TELFAST® 180 has not been studied in children under the age of 12 years (see section 4.3).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of TELFAST® 180 is important. It allows continued monitoring of the benefit/risk balance of TELFAST® 180. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8, or to the Pharmacovigilance Unit at Sanofi at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

4.9 Overdose

Symptoms of overdose

Most reports of TELFAST® 180 overdose contain limited information. However, dizziness, drowsiness and dry mouth have been reported.

Management of overdose

Standard measures should be considered to remove any unabsorbed medicine. Haemodialysis does not effectively remove fexofenadine hydrochloride from blood.

Paediatric population

No data are available.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fexofenadine hydrochloride belongs to the medicine class A 5.7.1 Antihistamines.

Fexofenadine hydrochloride is a pharmacologically active metabolite of terfenadine and is a non-sedating selective histamine H_1-receptor antagonist.

Fexofenadine exhibits an antihistaminic effect beginning within one hour, achieving maximum effect at 6 hours and lasting 24 hours. There was no evidence of tolerance to these effects after 28 days of dosing.

Paediatric population

The efficacy and safety of TELFAST® 180 in children under 12 has not been studied (see section 4.2 and 4.4).

5.2 Pharmacokinetic properties

Absorption:

Fexofenadine is absorbed into the body following oral administration, with Tmax occurring at approximately 1 - 3 hours post dose. The mean Cmax value was approximately 494 ng/ml following the administration of a 180 mg dose once daily.

Distribution:

Fexofenadine is 60 – 70 % plasma protein bound.

Biotransformation:

Fexofenadine undergoes negligible metabolism, as it was the only major compound identified in urine and faeces of animals and man.

Elimination:

The plasma concentration profiles of fexofenadine follow a bi-exponential decline with a terminal elimination half-life ranging from 11 to 15 hours after multiple dosing. The single and multiple dose pharmacokinetics of fexofenadine are linear between 40 mg and 240 mg taken daily. The major route of elimination is believed to be via biliary excretion while up to 10 % of ingested dose is excreted unchanged through the urine.

Special populations:

The elderly: (see section 4.2 and 4.4).

In older subjects (≥ 65 years old), peak plasma levels of fexofenadine were 99 % greater than those observed in normal volunteers (< 65 years old). Mean elimination half-lives were similar to those observed in normal volunteers.

Renally impaired: (see section 4.2 and 4.4).

In patients with mild (creatinine clearance 41-80 mL/min) to severe (creatinine clearance 11-40 mL/min) renal impairment, peak plasma levels of fexofenadine were 87 % and 111 % greater, respectively, and mean elimination half-lives were 59 % and 72 % longer, respectively, than observed in normal volunteers. Peak plasma levels in patients on dialysis (creatinine clearance ≤ 10 mL/min) were 82 % greater and half-life was 31 % longer than observed in normal volunteers. Based on increases of bioavailability and half-life, a dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function. (See section 4.2 and 4.4).

Patients with a history of or ongoing cardiovascular disease should be warned that, antihistamines as a medicine class have been associated with the adverse reactions, tachycardia and palpitations (see section 4.2 and 4.8).

Paediatric population

No data are available

5.3 Preclinical safety data

No data are available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Croscarmellose Sodium

Pre-gelatinised Maize Starch

Microcrystalline Cellulose

Magnesium Stearate

Film coat:

Hypromellose E-15

Hypromellose E-5

Povidone

Titanium Dioxide (E171)
Colloidal anhydrous silica
Pink Iron Oxide Blend
Yellow Iron Oxide Blend
Macrogol 400

6.2 Incompatibilities

No data are available

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store in a well-closed container at or below 25 °C.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Blister strips of 5, 10 or 15 tablets are packed into cartons of 5, 10 or 30 tablets.
Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Opella Healthcare South Africa (Pty) Ltd
4th Floor, Building I, Hertford Office Park,
90 Bekker Road, Midrand, 1652
Tel. no.: 011 256 3700

8. REGISTRATION NUMBER

32/5.7.1/0447

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

08 February 1999

10. DATE OF REVISION OF THE TEXT

5 October 2022

Namibia
Scheduling status: NS1
Registration number:
04/5.7.1/0387

Professionele Inligting vir TELFAST® 180 tablette

SKEDULERINGSTATUS

S1

1. NAAM VAN DIE MEDISYNE

TELFAST® 180 tablette

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

Elke filmbedekte tablet bevat feksofenadienbasis 168 mg (as feksofenadienhidrochloried 180 mg)

Suikervry.

Vir die volledige lys toevoegings, sien afdeling 6.1.

3. FARMASEUTIESE VORM

Filmbedekte tablette

Perskekleurige, kapsuulvormige, filmbedekte tablette. Aan die een kant is die syfer “018” gedruk, aan die ander kant, ‘n “e”.

Deursnit: ongeveer 7,6 mm x 17,3 mm.

Dikte: ongeveer 5,3 mm.

4. KLINIESE BESONDERHEDE

4.1 Terapeutiese indikasies

TELFAST® 180 is aangedui vir die verligting van simptome wat verband hou met kroniese idiopatiese urtikarie (KIU).

TELFAST® 120 is aangedui vir die verligting van simptome wat verband hou met seisoenale allergiese rinitis (SAR), in volwassenes en kinders ouer as 12 jaar, waar TELFAST® 120 die simptome onvoldoende beheer het.

4.2 Dosering en metode van aanwending

Dosering

Volwassenes en kinders 12 jaar en ouer:

Een 180 mg tablet een keer per dag.

Spesiale populasies

Daar is slegs beperkte data beskikbaar oor die gebruik by bejaarde pasiënte of pasiënte met ingekorte nier- of lewerfunksie. TELFAST® 180 moet met omsigtigheid toegedien word in hierdie spesiale risikogroep (sien afdeling 4.2 en 5.2).

Pasiënte met ‘n geskiedenis van voortdurende kardiovaskulêre siekte moet gemaan word dat antihistamiene as ‘n medisyne klas geassosieer is met die newe-effekte, tagikardie en palpitasies (sien afdeling 4.4, 4.8 en 5.2).

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST® 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.4).

Metode van aanwending

Mondelingse toediening.

Die filmbedekte tablet moet nie gekou word nie.

4.3 Kontra-indikasies

TELFAST® 120 is teenaangedui by pasiënte met ‘n geskiedenis van hipersensitiwiteit vir feksofenadienhidrochloried of enige bestanddeel daarvan, soos gelys in afdeling 6.1.

Daar is geen ondervinding in die gebruik TELFAST® 180 in swanger vroue nie.TELFAST® 180 moet nie tydens swangerskap of deur moeders wat hul babas borsvoed, ingeneem word nie (sien afdeling 4.6).

4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik

Daar is slegs beperkte data beskikbaar oor die gebruik by bejaarde pasiënte of pasiënte met ingekorte nier- of lewerfunksie. TELFAST® 120 moet met omsigtigheid toegedien word in hierdie spesiale risikogroep (sien afdeling 4.2 en 5.2).

Pasiënte met ‘n geskiedenis van voortdurende kardiovaskulêre siekte moet gemaan word dat antihistamiene as ‘n medisyne klas geassosieer is met die newe-effekte, tagikardie en palpitasies (sien afdeling 4.4, 4.8 en 5.2).

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST® 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2).

4.5 Interaksie met ander medikasie en ander vorms van interaksie

TELFAST® 120 ondergaan nie hepatiese biotransformasie nie. Die gelyktydige toediening van TELFAST® 120 met eritromisien of ketokonasool het die vlak van feksofenadien in plasma, 2-3 keer laat styg. Die veranderings het nie gepaard gegaan met enige uitwerking op die QT-interval nie en is nie geassosieer met enige toename in newe-effekte in vergelyking met dié wanneer die middels afsonderlik toegedien is nie.

Toetse op diere het getoon dat die toename in die plasmavlakke van TELFAST® 120 wat na die gelyktydige toediening met eritromisien of ketokonasool waargeneem is, waarskynlik toegeskryf kan word aan verhoogde gastroïntestinale absorpsie, asook aan ’n afname in ó f galuitskeiding ó f gastroïntestinale sekresie, onderskeidelik.

Geen interaksie is tussen TELFAST® 120 en omeprasool waargeneem nie. Die toediening van ‘n teensuurmiddel wat aluminium- en magnesiumhidroksied jels bevat, 15 minute voor die toediening van TELFAST® 120, het egter ‘n afname in die biobeskikbaarheid tot gevolg gehad, waarskynlik toe te skryf aan binding in die gastroïntestinale kanaal. Dit is raadsaam om minstens 2 ure te laat verloop, tussen die toediening van TELFAST® 120 en aluminium- en magnesiumhidroksied-bevattende teensuurmiddels.

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST® 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2 en 4.4).

4.6 Fertiliteit, swangerskap en borsvoeding

Swangerskap

Daar is geen ondervinding in die gebruik van TELFAST® 120 in swanger vroue nie. TELFAST® 120 moet nie tydens swangerskap gebruik word nie (sien afdeling 4.3).

Borsvoeding

TELFAST® 120 moet nie deur moeders wat hul babas borsvoed, ingeneem word nie (sien afdeling 4.3).

Fertiliteit

Geen data is beskikbaar nie.

4.7 Effek op die vermoë om te bestuur en masjienerie te gebruik

TELFAST® 180 het nie sederende effekte nie. Pasiënte word nogtans gemaan dat ‘n klein hoeveelheid individue wél ‘n sederende effek mag ervaar. Dit is daarom raadsaam om individuele reaksie op die middel te toets, voordat ’n motor bestuur, of ingewikkelde take aangepak word. Hierdie effek mag vererger word deur die gelyktydige inname van alkohol of ander sentrale senuweesisteem depressante.

4.8 Newe-effekte

Waar van toepassing, is die volgende frekwensie-beoordeling gebruik:

Baie algemeen: (>1/10); Algemeen: (>1/100, <1/10); Ongewoon:

(> 1/1000, <1/100); Seldsaam: (> 1/10 000, <1/1000); Baie seldsaam: (<1/10 000), insluitend ‘geisoleerde gevalle’.

Senuweesisteem afwykings:

Algemeen: Hoofpyn, hoofpyn, duiseligheid.

Gastro-intestinale afwykings:

Algemeen: Naarheid.

Algenene afwykings en plek-van-toediening toestande:

Ongewoon: Moegheid.

Immuunsisteem afwykings:

Ongewoon: Hipersensitiwiteitsreaksies met manifestasies soos angio-edeem, beklemming van die borskas, dispnee, gloede en sistemiese anafilakse.

Psigiatriese afwykings:

Ongewoon: Slapeloosheid, senuagtigheid en slaapstoornisse.

Senuweesisteem afwykings:

Ongewoon: Paroniria.

Kutaneuse- en subkutaneuse weefsel afwykings:

Ongewoon: Uitslag, urtikarie, pruritis.

Die volgende newe-effekte is tydens na-bemarking-waarneming in volwassenes aangemeld. Die frekwensie waarteen dit plaasgevind het, is nie bekend nie (kan nie uit beskikbare data geskat work nie).

Ongewoon: Hartafwykings

Tagikardie, palpitasies

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST® 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2 en 4.4).

Rapportering van vermoede ongunstige reaksies

Rapportering van vermoede ongustige reaksies, na die goedkeuring van TELFAST® 120 is belangrik. Dit laat toe vir die voortdurende monitering van die voordeel/risiko balans van

TELFAST® 120. Gesondheidsdiens verskaffers word gevra om enige vermoede ongunstige reaksies aan SAHPRA te rapporteer, via die "6.04 Adverse Drug Reactions Reporting Form", wat gevind kan word onder SAHPRA se publikasies;

- **https://www.sahpra.org.za/Publications/Index/8, óf aan die**
- **Waaksaamheidseenheid van Sanofi by za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).**

4.9 Oordosering

Simptome van oordosering

Die meeste verslae oor TELFAST® 120 oordosering bevat beperkte inligting. Nietemin is duiseligheid, lomerigheid en droë mond aangemeld.

Behandeling van oordosering

Standaard prosedures behoort oorweeg te word vir die verwydering van enige ongeabsorbeerde geneesmiddel. Hemodialise verwyder nie feksofenadienhidrochloried doeltreffend uit die bloed nie.

Pediatriese populasie

Geen data is beskikbaar nie.

5. FARMAKOLOGIESE EIENSKAPPE

5.1 Farmakodinamiese eienskappe

Feksofenadien behoort tot die medisyne-klas A 5.7.1 Antihistamiene.

Feksofenadienhidrochloried is 'n farmakologies-aktiewe metaboliet van terfenadien en is 'n nie-sederende,selektiewe histamien H_1-reseptor antagonis.

Feksofenadien toon 'n antihistaminergiese effek binne een uur en bereik 'n maksimum effek na 6 uur, wat 24 uur lank duur. Daar was geen bewys van toleransie teen hierde uitwerkings na 28 dae se toediening nie.

Pediatriese populasie

Die doeltreffendheid en veiligheid van TELFAST® 120 by kinders onder die ouderdom van 12 jaar is nog nie vasgestel nie (sien afdeling 4.2 en 4.4).

5.2 Farmakokinetiese eienskappe

Absorpsie

Feksofenadien word na mondelingse toediening deur die liggaam geabsorbeer en T_{maks} word ongeveer 1-3 uur na toediening bereik. Die gemiddelde K_{maks}-waarde was ongeveer 427 ng/ml na toediening van ‘n 120 mg dosis een keer per dag.

Verspreiding

Feksofenadien is 60 - 70 % plasmaproteïen gebonde.

Biotransformasie

Feksofenadien ondergaan geringe metabolisme, aangesien dit die enigste noemenswaardige produk is wat in dierlike en menslike uriene en feses voorgekom het.

Eliminasie

Die plasmakonsentrasie profiele van feksofenadien volg ‘n bi-eksponesiële afname met ‘n terminale eliminasie halfleeftyd wat wissel tussen 11 tot 15 uur na herhaalde inname. Die enkel- en meervoudige dosis farmakokinetika van feksofenadien is lineêr tussen daaglikse dossise van 40 mg en 240 mg.Die vernaamste eliminasie roete is waarskynlik galuitskeiding, terwyl tot 10 % van die dosis wat ingeneem is, onveraderd deur die uriene uitgeskei word.

Spesiale populasies

Bejaardes: (sien afdeling 4.2 en 4.4).

In ouer persone (≥ 65 jaar oud), was piek plasmavlakke van feksofenadien 99 % groter as dié waargeneem in normale vrywilligers (< 65 jaar oud). Gemiddelde eliminasie halfleeftye was soortgelyk as dié waargeneem in normale vrywilligers.

Renale inkorting: (sien afdeling 4.2 en 4.4).

In pasiënte met matige (kreatinienopruiming 41 - 80 mL/min) tot erge (kreatinienopruiming 11 - 40

mL/min) renale inkorting, was piek plasmavlakke van feksofenadien onderskeidelik 87 % en 111 % hoër, en gemiddelde eliminasie halfleeftye onderskeidelik 59 % en 72 % langer, as dié waargeneem in normale vrywilligers. Piek plasmavlakke in pasiënte op dialise (kreatinienopruiming ≤ 10 mL/min) was 82 % hoër en halfleeftyd was 31 % langer as dié waargeneem in normale vrywilligers. Gegrond op dié toename in biobeskikbaarheid en halfleeftyd, word ‘n aanvangsdosis van 60 mg een keer per dag aanbeveel vir pasiënte met ingekorte nierfunksie (sien afdeling 4.2 en 4.4).

Pasiënte met ‘n geskiedenis van voortdurende kardiovaskulêre siekte moet gemaan word dat antihistamiene as ‘n medisyne klas geassosieer is met die newe-effekte, tagikardie en palpitasies (sien afdeling 4.4 en 4.8).

Pediatriese populasie

Geen data is beskikbaar nie.

5.3 Pre-kliniese veiligheidsdata

Geen data is beskikbaar nie.

6. FARMASEUTIESE BESONDERHEDE

6.1 Lys van toevoegings

Tabletkern:

Natriumkroskarmellose

Pre-gegelatiniseerde mieliestysel

Mikrokristallyne sellulose

Magnesiumstereaat

Filmbedekking:

Hipromellose E-15

Hipromellose E-5

Povidoon

Titaandioksied (E171)

Kolloïdale anhidriese silika

Pienk silweroksied mengsel

Geel ysteroksied mengsel

Makrogool 400

6.2 Onverenigbaarhede

Geen data is beskikbaar nie.

6.3 Raklewe

TBC

6.4 Spesiale voorsorgmaatreëls vir berging

Berg in ‘n digsluitende houer teen of benede 25 °C.

HOU BUITE DIE BEREIK VAN KINDERS.

6.5 Aard en inhoud van houer

Stulpverpakte stroke van 5, 10 of 15 tablette is verpak in kartonne van 10 of 30 tablette.

Nie alle pakgroottes word noodwendig bemark nie.

6.6 Spesiale voorsorgmaatreëls vir wegdoening en ander hantering

Geen spesiale vereistes nie.

7. HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

Opella Healthcare South Africa (Edms) Bpk

4de Vloer, Gebou I, Hertford Kantoorpark,

Bekkerweg 90, Midrand, 1652

Tel. nr.: 011 256 3700

8. REGISTRASIE NOMMER(S)

32/5.7.1/0447

9. DATUM VAN EERSTE GOEDKEURING / HERNUWING VAN GOEDKEURING

08 Februarie 1999

10. DATUM VAN HERSIENING VAN TEKS

5 Oktober 2022

Namibië
Skeduleringstatus: NS1
Registration number:
04/5.7.1/0387