SCHEDULING STATUS: **S1**

PROPRIETARY NAMES (AND DOSAGE FORM): TELFAST® Suspension

COMPOSITION:

TELFAST Suspension contains 6 mg fexofenadine hydrochloride per ml. A 5 ml dose will provide 30 mg of fexofenadine hydrochloride.

Preservatives : Propyl paraben 0,034 % *m/v*, butylparaben 0,017 % *m/v* and disodium edetate 0,150 % *m/v*.

Contains sucrose and xylitol

PHARMACOLOGICAL CLASSIFICATION:

A 5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION:

Pharmacodynamics:

Mechanism of Action

Fexofenadine hydrochloride, the major active metabolite of terfenadine, is a non-sedating antihistamine with selective peripheral H_1-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.

Pharmacokinetics:

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 Paediatric 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.

Metabolism:

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 [^{14}C] 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 drug or the result of biliary excretion.

Renally Impaired:

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 Dosage And Directions For Use).

Hepatically Impaired:

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

Geriatric Subjects:

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 Subjects:

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.

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.

CONTRA-INDICATIONS:

TELFAST Suspension is contra-indicated in patients with known hypersensitivity to any of the ingredients.

WARNINGS:

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.

INTERACTIONS:

Erythromycin and Ketoconazole

Co–administration of fexofenadine hydrochloride 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 fexofenadine hydrochloride 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 Pharmacokinetics and Dosage and Directions for Use).

PREGNANCY AND LACTATION:

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

Lactation

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 drugs are excreted in human milk, caution should be exercised when TELFAST is administered to a nursing woman.

DOSAGE AND DIRECTIONS FOR 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 (see Pharmacological Action, Pharmacokinetics).

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 Pharmacological Action, Pharmacokinetics).

Shake bottle well, before each use.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

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 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.

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

Special Precautions*:*

TELFAST Suspension lacks significant sedative effects.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

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.

Standard measures should be considered to remove any unabsorbed drug.

Symptomatic and supportive treatment is recommended. Haemodialysis does not effectively remove fexofenadine from blood.

IDENTIFICATION:

A white, uniform suspension with a raspberry cream aroma.

PRESENTATION:

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

STORAGE INSTRUCTIONS:

Store at or below 25°C.

Keep well closed

Shake the bottle well, before each use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER: 42/5.7.1/0339

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

sanofi-aventis south africa (pty) ltd

2 Bond Street, Midrand, 1685, South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

18 November 2010

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.CHCdrugsafety@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

18 July 2022

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

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This leaflet was last revised in

11 May 2022

Registration number

32/5.7.1/0447