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**
2. **What you need to know before you take TELFAST 120**
3. **How to take TELFAST 120**
4. **Possible side effects**
5. **How to store TELFAST 120**
6. **Contents of the pack and other information**

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

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