

APPROVED PATIENT INFORMATION LEAFLET FOR TELFAST 180 TABLETS

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

1. **What TELFAST 180 is and what it is used for**
2. **What you need to know before you take TELFAST 180**
3. **How to take TELFAST 180**
4. **Possible side effects**
5. **How to store TELFAST 180**
6. **Contents of the pack and other information**

1. 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 and Rashes and hay fever.

2. 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**

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 and breastfeeding

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.

3. How to take TELFAST 180

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

Check with your doctor or 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 or 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,

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 hospitalization.

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 or pharmacist or nurse.

You can also report side effect 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>.

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 °C.

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 Certificate of Registration

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