

## PROPOSED PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S2

**FEXOGEN 120** (120 mg film-coated tablet)

**FEXOGEN 180** (180 mg film-coated tablet)

Fexofenadine hydrochloride

Sugar free

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

Fexogen is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Fexogen carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Fexogen 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 Fexogen is and what it is used for
2. What you need to know before you take Fexogen
3. How to take Fexogen
4. Possible side effects
5. How to store Fexogen
6. Contents of the pack and other information

## 1. What Fexogen is and what it is used for

Fexogen contains the active ingredient fexofenadine hydrochloride and belongs to a group of medicines called antihistamines. It works by blocking the action of histamine and other substances produced by the body which are causing your allergies.

Fexogen is used to relieve the symptoms of hayfever (seasonal allergic rhinitis) such as sneezing, itchy, watery or red eyes and itchy, blocked or runny nose.

The 180 mg tablets are also used to relieve the symptoms of urticaria, otherwise known as hives or itchy rash.

## 2. What you need to know before you take Fexogen

### Do not take Fexogen if:

- you are hypersensitive (allergic) to fexofenadine hydrochloride or any of the other tablet ingredients of Fexogen (listed in section 6).
- you are under the age of 12
- you are pregnant or planning to become pregnant
- or you are breastfeeding

## Warnings and precautions

### Take special care with Fexogen if:

- you are over the age of 60
- you have kidney or liver problems
- you are performing skilled tasks (such as driving), as you may experience drowsiness

## Other medicines and Fexogen

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

Speak to your doctor or pharmacist:

If you are taking erythromycin or ketoconazole together with Fexogen.

If you are taking apalutamide (a medicine to treat prostate cancer), as the effect of fexofenadine may be decreased.

If you are taking antacids containing aluminium and magnesium hydroxide, take the Fexogen and the antacid, 2 hours apart.

### **Pregnancy, breastfeeding and fertility**

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.

You should not take Fexogen if you are pregnant or breastfeeding your baby.

### **Driving and using machines**

It is not always possible to predict to what extent Fexogen may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Fexogen affects them.

Although drowsiness is rare, it can occur and may affect the performance of skilled tasks.

### **3. How to take Fexogen**

Do not share medicines prescribed for you with any other person.

Always take Fexogen exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

For relief of the symptoms of hayfever, the usual dosage for adults and children over 12 years of age is one 120 mg tablet daily when required.

For relief of the symptoms of urticaria, the usual dosage for adults and children over 12 years of age is one 180 mg tablet daily when required.

If you have poor kidney function, a lower starting dose of 60 mg is recommended.

If you have the impression that the effect of Fexogen is too strong or too weak, talk to your doctor or pharmacist.

**If you take more Fexogen than you should:**

You may experience dizziness, drowsiness and dry mouth.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

**If you forget to take Fexogen:**

Take the tablet the next day. Do not take a double dose to make up for forgotten individual doses.

**4. Possible side effects**

Fexogen can have side effects.

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

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

- Hypersensitivity reactions with manifestations such as swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Chest tightness, difficulty in breathing, flushing and itching, wheezing, a sudden

drop in blood pressure (systemic anaphylaxis).

These are all very serious side effects. If you have them, you may have had a serious reaction to Fexogen. 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
- Dizziness
- Nausea

*Less frequent side effects*

- Difficulty sleeping
- Nervousness
- Sleep disorders
- Nightmares and excessive dreaming
- Chest tightness
- Difficulty breathing
- Flushing (becoming red and or hot)
- Rash
- Itching
- Tiredness

*Frequency not known*

- Blurred vision

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, 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>. By reporting side effects, you can help provide more information on the safety of Fexogen.

### **5. How to store Fexogen**

Store your tablets in a cool place (below 25 °C), in the original containers.

Keep all medicines out of the reach and sight of children.

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 Fexogen contains**

- The active substance is fexofenadine hydrochloride, 120 mg per tablet in Fexogen 120 and 180 mg per tablet in Fexogen 180.
- The other ingredients are microcrystalline cellulose, croscarmellose sodium, maize starch, povidone, magnesium stearate, hydroxypropylmethylcellulose, titanium dioxide, polyethylene glycol 400, polyethylene glycol 4000, iron oxide yellow CI177492 and iron oxide red CI177491 (120 mg tablets only).

Applicant: Trinity Pharma (Pty) Ltd  
Application name (number): Fexogen 120/180 (400083-4)

### **What Fexogen looks like and contents of the pack**

Fexogen 120: Peach coloured, oblong, biconvex film-coated tablet, plain on both sides.

Fexogen 180: Yellow coloured, oblong, biconvex film-coated tablet, plain on one side and scored on the other.

Fexogen 120 is packed in blister strips and are placed in outer cardboard cartons of 10 or 30 tablets.

Fexogen 180 is packed in blister strips and are placed in outer cardboard cartons of 10 or 30 tablets.

### **Holder of Certificate of Registration**

Trinity Pharma (Pty) Ltd.  
106 16th Road, Building 2  
Midrand  
1686

### **This leaflet was last revised in**

05 June 2024

### **Registration number**

Fexogen 120: A40/5.7.1/0083

Fexogen 180: A40/5.7.1/0084

### **Access to the corresponding Professional Information**

[www.trinitypharma.co.za](http://www.trinitypharma.co.za)