PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

FENOFEX 120 Tablets

FENOFEX 180 Tablets

Fexofenadine hydrochloride

Sugar free

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

- This medicine is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use FENOFEX carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share FENOFEX with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What FENOFEX is and what it is used for

2. What you need to know before you take FENOFEX

3. How to take FENOFEX

4. Possible side effects

5. How to store FENOFEX

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1. What FENOFEX is and what it is used for

FENOFEX is an antihistamine which has an anti-allergy action.

FENOFEX 120 tablets are used to relieve symptoms like sneezing, itchy, runny nose, and itchy, red and watery eyes associated with hay fever (seasonal allergic rhinitis).

FENOFEX 180 tablets are used to relieve symptoms such as swelling, itching and redness associated with an allergic skin condition known as chronic idiopathic urticaria.

2. What you need to know before you take FENOFEX

Do not take FENOFEX 120 or 180:

- If you are hypersensitive (allergic) to fexofenadine or any other ingredients of FENOFEX (listed in section 6).

  (An allergic reaction may include rash, itching, swelling of the lips or hands/feet or breathing difficulties).
- if you are pregnant or planning to become pregnant or are breast feeding.
- if you are a child under 12 years of age as safety and effectiveness of FENOFEX 120 and 180 have not been established.

Warnings and precautions

Take special care with **FENOFEX**:

- If you are elderly or have problems with your kidneys and/ or liver.
- When you start taking FENOFEX it may affect your ability to drive or use machinery.
- FENOFEX tablets are not known to have sedative effects. However, a small number of patients may experience sedation.
- If you are taking alcohol or other medicines that cause sedation as you may experience sedation.
- You have ever had heart disease since this medicine may lead to fast or irregular heartbeat.

Other medicines and FENOFEX

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

traditional medicines).

Care is needed if**:**

- You are taking erythromycin (an antibacterial, used for treating infections due to certain bacteria).
- You are taking ketoconazole (an antifungal, used for treating infections due to certain fungi).
- You are taking antacids containing aluminium hydroxide and magnesium hydroxide (used for treating indigestion). These products can reduce the absorption of fexofenadine. If it is essential that you take these products, it is recommended that you leave at least 2 hours between the time that you take FENOFEX 120 or 180 tablets and your indigestion medicine.
- You are taking apalutamide (a medicine to treat prostate cancer), as the effect of fexofenadine may be decreased.
- If you are taking medicines on a regular basis, including complementary or traditional medicines, the use of FENOFEX 120 or 180 with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

FENOFEX with food or drink

FENOFEX may be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy:

Do not take FENOFEX if you are pregnant or planning to become pregnant.

Breastfeeding:

If you are taking FENOFEX you should not breastfeed your baby**.**

Driving and using machines

FENOFEX causes dizziness and drowsiness which may affect your ability to drive or operate machinery.

3. How to take FENOFEX

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

Always take FENOFEX exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

Adults and children aged 12 years and over:

For the treatment of seasonal allergic rhinitis (hay fever) take one FENOFEX 120 tablet once daily.

For the treatment of chronic idiopathic urticaria take one FENOFEX 180 tablet once daily.

Swallow the tablet whole with a glass of water.

Elderly and patients with liver or kidney disease

The starting dose for patients with liver disease or decreased kidney function is to take half a FENOFEX 120 tablet once a day.

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

If you have taken more FENOFEX than you should

You may feel dizziness, drowsiness and dry mouth.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take FENOFEX

Take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

To help you remember to take your medicine, try to get into the habit of taking it at the same time each day.

4. Possible side effects

FENOFEX can have side effects.

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

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

- Rashes, hives, itching, chest constriction, shortness of breath or swelling of the face, lips, tongue, hands/ feet, fainting, high temperature.

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

Tell your doctor if you notice any of the following:

Frequent:

- headache,
- dizziness,
- drowsiness,
- nausea.

Less frequent:

- sinus infections,
- viral infections such as cold or flu,
- hypersensitivity reactions with presentations such as tender red lumps under the skin, chest tightness, difficult or laboured breathing, flushing and severe allergic reactions,
- tiredness,
- insomnia,
- nervousness,

- sleep disorders or a nightmares/excessive dreaming (paroniria),
- dyspepsia,
- rash, urticaria and pruritis,
- dysmenorrhoea,
- fast or irregular heartbeat
- diarrhoea.

Not known (frequency cannot be estimated from the available data):

- 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 FENOFEX.

5. How to store FENOFEX

Store all medicines out of reach of children.

- Store at or below 25 °C, protected from moisture in the original carton.
- Protected from light/moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- 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 FENOFEX contains

The active substance is fexofenadine hydrochloride.

The other ingredients are croscarmellose sodium, magnesium stearate, microcrystalline cellulose, coating agent Opadry brown, printing ink Opacode S-1-27794 and povidone.

These tablets are sugar free.

What FENOFEX looks like and contents of the pack

FENOFEX 120

Pink coloured, capsule shaped, coated tablets imprinted with 'F1' in black ink on one side and plain on the other side.

FENOFEX 180

Pink coloured, capsule shaped, coated tablets imprinted with 'F2' in black ink on one side and plain on the other side.

Contents of the pack:

FENOFEX 120

Tablets are packed in white, opaque, PVC/PVDC blister strips with an aluminium foil backing. Cartons contain 10 or 30 tablets.

FENOFEX 180

Tablets are packed in white, opaque, PVC/PVDC blister strips with an aluminium foil backing. Cartons contain 10 or 30 tablets.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

14 Lautre Road, Stormill Ext 1

Roodepoort, 1724 , South Africa

This leaflet was last revised in

30 December 2023

Registration number

FENOFEX 120: A38/5.7.1/0407

FENOFEX 180: A38/5.7.1/0408