

PATIENT INFORMATION LEAFLET FOR
FEXO 120 FILM COATED TABLETS
FEXO 180 FILM COATED TABLETS

SCHEDULING STATUS

S1

FEXO 120 mg film-coated tablets

FEXO 180 mg film-coated tablets

Fexofenadine hydrochloride

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share FEXO with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve 5 after days.

What is in this leaflet

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

1. What FEXO is and what it is used for

FEXO belongs to the group of medicines known as antihistamines.

FEXO 120 is used to treat symptoms associated with seasonal allergic rhinitis (allergies) such as stuffy or runny nose; sneezing; postnasal drip and red, itchy, watery eyes.

FEXO 180 is used to treat symptoms associated with chronic hives (chronic idiopathic urticaria) such as itchy red or white wheals on the skin which vary in size shape.

2. What you need to know before you take FEXO

Do not take FEXO if you:

- are hypersensitive (allergic) to fexofenadine or any of the other ingredients of FEXO (listed in **section 6**).
- if you are pregnant or breast feeding your baby (see **Pregnancy, breastfeeding and fertility**).

Warnings and Precautions

Special care should be taken with FEXO:

- If you are elderly
- If you have kidney problems (may include symptoms such as weakness, shortness of breath, lethargy, swelling, and confusion)
- If you have liver problems (may include symptoms such as skin and eyes that appear yellowish (jaundice), stomach pain and swelling, swelling in the legs and

ankles, itchy skin, chronic fatigue, nausea or vomiting, loss of appetite, tendency to bruise easily)

- If you have a history of or current heart problems (symptoms vary widely, ranging from chest pain to rapid heartbeat) as it may cause an irregular heartbeat.
- If you feel sedated (sleepy) after taking FEXO
- If you are drinking alcohol or taking other medicines that slow brain activity such as sedatives or tranquilizers (central nervous system depressants) while taking FEXO.

Children

Do not give to children under the age of 12 years.

Other medicines and FEXO

Always tell your healthcare provider if you are taking any other medicines (this includes all complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Erythromycin: medicine used to treat bacterial infections
- Ketoconazole: medicines used to treat fungal infections
- If you are taking apalutamide (a medicine to treat prostate cancer), as the effect of fexofenadine may be decreased.
- Antacids containing aluminium and magnesium hydroxide gels: medicines used to relieve heartburn or an upset stomach. It is advisable to leave 2 hours between taking FEXO and antacids containing aluminium and magnesium hydroxide gels

- Central nervous system depressants: medicines that slow down the activity in the brain or make you feel drowsy or less alert.

FEXO with food, drink and alcohol:

FEXO tablets should be taken whole with a glass of water before a meal. Do not take FEXO with alcohol as this could enhance FEXO's sedative effect (it could make you drowsy or sleepy).

Pregnancy, breastfeeding and fertility

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

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 healthcare provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent FEXO 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 FEXO affects them (see **section 4**).

3. How to take FEXO

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

Always take FEXO exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Adults and children aged 12 years and over:

Symptoms associated with long term allergic skin reactions such as itching, swelling and rashes of the skin (chronic idiopathic urticaria): One 180 mg tablet daily.

Symptoms associated with hay fever such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes (seasonal allergic rhinitis): One 120 mg tablet daily.

Children under 12 years of age:

The efficacy and safety of FEXO has not been studied in children under 12.

If you have problems with your kidneys, a dose of 60 mg once daily is recommended as the starting dose.

Your doctor will tell you how long your treatment with FEXO will last.

If you have the impression that the effect of FEXO is too strong or too weak, tell your doctor or pharmacist.

If you take more FEXO than you should

In the event of overdose, consult your pharmacist or doctor. If neither is available, contact the nearest hospital or poison control center. As a result of overdose you may experience the following side effects:

- Dizziness
- Drowsiness
- Dry mouth.

If you forget to take FEXO

Do not take a double dose to make up for forgotten individual doses.

4. Possible Side Effects

FEXO can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- chest tightness, difficulty in breathing (dyspnoea), flushing, 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 allergic reaction to FEXO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- rapid irregular action of the heart; irregular heartbeat (tachycardia, palpitations).

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- headache, drowsiness, dizziness

- feeling sick (nausea).

The following side effects have been reported less frequently:

- tiredness (fatigue)
- chest tightness, difficulty breathing
- flushing (becoming red and/or hot).
- difficulty sleeping (insomnia), nervousness, sleep disorders or nightmares (paranoia)

The following side effects have been reported but the frequency is unknown:

- frequent/loose watery stools (diarrhoea), heartburn or indigestion (dyspepsia)
- blurred vision.
- fast or irregular heartbeat

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafety@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of FEXO.

5. How to store FEXO

- Store at or below 25 °C.
- Keep the blister strips in the carton until required for use.
- Store all medicines out of reach of children.

- Do not store in a bathroom.
- Do not use after the expiry date stated on the packaging material.
- 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 FEXO contains:

FEXO 120

The active substance is 120 mg of fexofenadine hydrochloride.

The other ingredients are croscarmellose sodium, magnesium stearate, maize starch, microcrystalline cellulose, opadry (03C54667) (containing hypromellose, iron oxide red, iron oxide yellow, macrogol 400, macrogol-4000 and titanium dioxide), and povidone.

FEXO 180

The active substance is 180 mg of fexofenadine hydrochloride.

The other ingredients are croscarmellose sodium, magnesium stearate, maize starch, microcrystalline cellulose, opadry (03C54667) (containing hypromellose, iron oxide yellow, macrogol 400, macrogol-4000 and titanium dioxide), and povidone.

What FEXO looks like and contents of the pack

FEXO 120: Peach coloured, oblong, biconvex, film-coated tablets with a breakline on one side and plain on the other side.

FEXO 120: Packed in transparent PVC and aluminium foil blister strips with 5, 10 or 15 tablets,
packed in cartons of 5, 10 or 30 tablets.

FEXO 180: Yellow coloured, oblong, biconvex, film-coated tablets, plain on one side and central
breakline on the other side.

FEXO 180: Packed in transparent PVC and aluminium foil blister strips with 5, 10 or 15 tablets,
packed in cartons of 5, 10 or 30 tablets.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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FEXO 180: A38/5.7.1/0415

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to be
generated and included
after approval.

Botswana: S2

FEXO 120 mg: BOT0801100

FEXO 180 mg: BOT0801099

Namibia: NS1

FEXO 180 mg: 9/5.7.1/0016

FEXO 180 mg: 09/5.7.1/0017