

<b>Applicant:</b> Oethmaan Biosims (Pty) Ltd	<b>SAHPRA approval date:</b> 3 September 2024
<b>Product:</b> FEXOFENADINE 120 mg MEDREICH	<b>Dosage form and strength:</b> Each film-coated tablet contains: 120 mg Fexofenadine Hydrochloride

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

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### FEXOFENADINE 120 mg MEDREICH, film-coated tablet

Fexofenadine Hydrochloride 120 mg

Contains sugar (lactose monohydrate 152.42 mg)

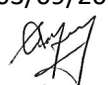
### Read all of this leaflet carefully because it contains important information for you

FEXOFENADINE 120 mg MEDREICH is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FEXOFENADINE 120 mg MEDREICH carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FEXOFENADINE 120 mg MEDREICH with any other person.
- Ask your doctor or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

### What is in this leaflet

1. What FEXOFENADINE 120 mg MEDREICH is and what it is used for
2. What you need to know before you take FEXOFENADINE 120 mg MEDREICH
3. How to take FEXOFENADINE 120 mg MEDREICH

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4. Possible side effects
5. How to store FEXOFENADINE 120 mg MEDREICH
6. Contents of the pack and other information

### 1. What FEXOFENADINE 120 mg MEDREICH is and what it is used for

FEXOFENADINE 120 mg MEDREICH contains fexofenadine hydrochloride which belongs to a group of medicines called antihistamines.

FEXOFENADINE 120 mg MEDREICH: 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, itchy, runny or blocked nose and itchy, red and watery eyes.

### 2. What you need to know before you take FEXOFENADINE 120 mg MEDREICH


**Do not take FEXOFENADINE 120 mg MEDREICH if:**

- you are hypersensitive (allergic) to fexofenadine hydrochloride or any of the other ingredients of FEXOFENADINE 120 mg MEDREICH (listed in section 6: **See what FEXOFENADINE 120 mg MEDREICH contains** below).
- you are pregnant or breastfeeding your baby.

### Warnings and precautions

Special caution should be taken with FEXOFENADINE 120 mg MEDREICH:

- If you have kidney disease.
- If you have liver disease.

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- If you have or ever had heart disease, since FEXOFENADINE 120 mg MEDREICH may lead to a fast or irregular heartbeat.
- If you are elderly.

If any of these apply to you, or you are not sure, inform your doctor or pharmacist before taking FEXOFENADINE 120 mg MEDREICH.

*Children:*

FEXOFENADINE 120 mg MEDREICH should not be given to children under the age of 12 years old as the safety and efficacy has not been studied.

**Other medicines and FEXOFENADINE 120 mg MEDREICH**

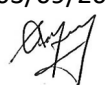
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

The following medicines may increase the level of FEXOFENADINE 120 mg MEDREICH in your blood:

- erythromycin (an antibiotic)
- ketoconazole (a medicine used to treat fungal infections)
- apalutamide (a medicine to treat prostate cancer).

The following medicine may lower the amount of FEXOFENADINE 120 mg MEDREICH in your blood:

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- Aluminium and magnesium hydroxide containing antacids for indigestion may affect the action of FEXOFENADINE 120 mg MEDREICH, by lowering the amount of medicine absorbed. It is recommended that you leave about 2 hours between the time that you take FEXOFENADINE 120 mg MEDREICH and your medicine for indigestion.

No interaction between FEXOFENADINE 120 mg MEDREICH and the medicine omeprazole (for ulcers and heartburn) was observed.

### **FEXOFENADINE 120 mg MEDREICH with food and drink and alcohol**

Taking FEXOFENADINE 120 mg MEDREICH with alcohol should be avoided.

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

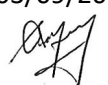
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking FEXOFENADINE 120 mg MEDREICH.

#### *Pregnancy*

You should not take FEXOFENADINE 120 mg MEDREICH when you are pregnant as there are no studies performed in pregnant women.

#### *Breastfeeding*

You should not breastfeed your baby when you are on FEXOFENADINE 120 mg MEDREICH treatment as FEXOFENADINE 120 mg MEDREICH may be secreted in breast milk.

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### *Fertility*

There are no studies of the effect of FEXOFENADINE 120 mg MEDREICH on human fertility.

### **Driving and using machines**

FEXOFENADINE 120 mg MEDREICH is unlikely to affect your ability to drive or operate machinery. However, you should check that FEXOFENADINE 120 mg MEDREICH does not make you feel sleepy or dizzy before driving or operating machinery. If you take alcohol or other sedatives, these effects may be worsened.

### **FEXOFENADINE 120 mg MEDREICH contains:**

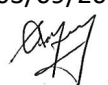
FEXOFENADINE 120 mg MEDREICH contains sugar (lactose monohydrate). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking FEXOFENADINE 120 mg MEDREICH.

### **3. How to take FEXOFENADINE 120 mg MEDREICH**

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

Always take FEXOFENADINE 120 mg MEDREICH exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

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*For adults and children aged 12 years and over:*

FEXOFENADINE 120 mg MEDREICH: The recommended dose is one tablet daily.

Take your tablet with water before a meal.

Do not chew the tablets.

**If you take more FEXOFENADINE 120 mg MEDREICH than you should**

In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

Symptoms of overdosage include dizziness, drowsiness and dry mouth.

**If you forget to take FEXOFENADINE 120 mg MEDREICH**

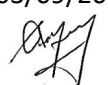
If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose.

In that case, just carry on with the next dose as normal.

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

**If you stop taking FEXOFENADINE 120 mg MEDREICH**

Tell your doctor or pharmacist if you want to stop taking FEXOFENADINE 120 mg MEDREICH before you have finished your course of treatment. If you stop taking FEXOFENADINE 120 mg MEDREICH earlier than planned, your symptoms may return.

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#### 4. Possible side effects:

FEXOFENADINE 120 mg MEDREICH can have side effects.

Not all side effects reported for FEXOFENADINE 120 mg MEDREICH are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking FEXOFENADINE 120 mg MEDREICH, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking FEXOFENADINE 120 mg MEDREICH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden signs of allergy – including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing, chest tightness and flushing.

These are all very serious side effects. If you have them, you may have had a serious reaction to FEXOFENADINE 120 mg MEDREICH. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

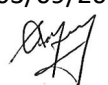
#### Frequent side effects

- Headache, drowsiness, dizziness
- Nausea

#### Less frequent side effects

- Difficulty sleeping, sleep disorders, bad dreams, excessive dreaming, nervousness
- Skin rash and itching, hives
- Tiredness

#### Frequency unknown

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- Fast or irregular heartbeat
- Diarrhoea
- 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 FEXOFENADINE 120 mg MEDREICH.

### 5. How to store FEXOFENADINE 120 mg MEDREICH

#### STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Protect from light and moisture.

Store in the original package/container.


Keep the HDPE container closed.

Keep the blister in the carton until required for use.

Do not store in a bathroom.

Do not use FEXOFENADINE 120 mg MEDREICH after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What FEXOFENADINE 120 mg MEDREICH contains

#### FEXOFENADINE 120 mg MEDREICH, film-coated tablet:

The active substance in each tablet is 120 mg fexofenadine hydrochloride.

The other ingredients are:

Lactose monohydrate, hydroxypropylcellulose, pregelatinised starch, colloidal anhydrous silica, microcrystalline cellulose, croscarmellose sodium, magnesium stearate. Film-coating containing hypromellose, polyvinylpyrrolidone, titanium dioxide, iron oxide red, iron oxide yellow, colloidal anhydrous silica and polyethylene glycol.

### What FEXOFENADINE 120 mg MEDREICH looks like and contents of the pack

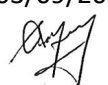
**FEXOFENADINE 120 mg MEDREICH, film-coated tablet:** Peach coloured capsule shaped film-coated tablets debossed as “120” on one side and “FX” on the other side.

FEXOFENADINE 120 mg MEDREICH is presented in the following packs:

#### 1. Alu/PVC/PVDC Blister Pack:

Alu/PVC/PVDC blister pack comprising of hard tempered aluminium foil and thick, white-opaque, well thermoformable PVC film coated with PVDC on outer side. This blister will be further packed in preprinted cartons along with package leaflet.

Pack sizes: 10 and 30 tablets.

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## 2. Alu/PVC/PE/ACLAR Blister Pack:

Alu/PVC/PE/ACLAR blister pack comprising of hard tempered aluminium foil and clear, transparent PVC film coated with ACLAR on other side, sandwiched with PE layer (Triplex film).

This blister will be further packed in preprinted cartons along with package leaflet.

Pack sizes: 10 and 30 tablets.

## 3. High Density Polyethylene (HDPE) Bottle Pack:

White opaque high density polyethylene (HDPE) bottle packs with white opaque polypropylene continuous threaded closure with wad having induction sealing liner.

Pack sizes: 500 and 1000 tablets.

Not all pack sizes may be marketed.

## Holder of Certificate of Registration

Oethmaan Biosims (Pty) Ltd

207A Sherwood House

Greenacres Office Park

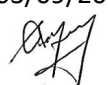
c/o Victory and Rustenburg Roads

Victory Park

Johannesburg

2195

Telephone number: 011 433 0602

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**This leaflet was last revised in**

3 September 2024

**Registration number**

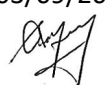
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**Access to the corresponding Professional Information**

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

Telephone number: 011 433 0602

Email: [info@oethmaan.co.za](mailto:info@oethmaan.co.za)

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