

**SCHEDULING STATUS:** S2

**Pollofex 120 (120 mg film-coated tablets)**

**Pollofex 180 (180 mg film-coated tablets)**

Fexofenadine hydrochloride

Pollofex 120 contains sugar (156 mg lactose monohydrate)

Pollofex 180 contains sugar (234 mg lactose monohydrate)

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

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

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

**1. What Pollofex is and what it is used for**

Pollofex tablets belong to a group of medicines called antihistamines.

Pollofex 120 is used to treat and relieve symptoms of seasonal allergic rhinitis (hay fever).

Pollofex 180 is used to treat and relieve symptoms of chronic idiopathic urticaria (chronic hives).

## **2. What you need to know before you take Pollofex**

### **Do not take Pollofex:**

- if you are hypersensitive (allergic) to fexofenadine hydrochloride or any of the other ingredients of Pollofex (listed in section 6).
- if you are pregnant or breastfeeding.

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

### **Warnings and precautions**

Take special care with Pollofex:

- if you are elderly
- if you have liver problems
- if you have kidney problems
- if you have a history of heart disease or ongoing heart disease, Pollofex may cause additional side effects (see Side Effects).

### **Children and adolescents**

Do not give Pollofex to children under the age of 12 years old because the safety and efficacy has not been studied.

### **Other medicines and Pollofex**

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

*The following medicines may increase the level of Pollofex in your blood:*

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

*The following medicine may lower the amount of Pollofex in your blood:*

- antacids, as it may decrease the absorption of Pollofex from your gut.

It is advisable to take Pollofex and antacids containing aluminium and magnesium hydroxide at least 2 hours apart.

No interaction between Biotech Fexofenadine and the medicine omeprazole was observed.

### **Pollofex with food and drink**

You may get drowsy or sleepy if you drink alcohol when taking Pollofex.

### **Pregnancy and breastfeeding**

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.

Do not take Pollofex if you are pregnant or breastfeeding your baby.

### **Driving and using machines**

Pollofex is unlikely to affect your ability to drive or operate machinery. A small number of individuals may experience sedation.

The simultaneous intake of alcohol or medicines called central nervous system depressants may lead to drowsiness and sedation.

It is not always possible to predict to what extent Pollofex may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or operate machines until you are aware of the measure to which Pollofex affects you.

### **Pollofex contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Pollofex.

### **3. How to take Pollofex**

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

Always take Pollofex 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 for adults and children aged 12 years and older is:

Pollofex 120: The usual dose is one 120 mg tablet once a day.

Pollofex 180: The usual dose is one 180 mg tablet once a day.

If you have decreased kidney function, the recommended starting dose is 60 mg once daily.

Take your tablet orally. Swallow your tablet with some water, do not chew the tablet.

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

### **If you take more Pollofex 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 overdose may include dizziness, drowsiness or a dry mouth.

### **If you forget to take Pollofex**

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

### **If you stop taking Pollofex**

The symptoms of your allergy may return if you stop taking Pollofex.

## **4. Possible side effects**

Pollofex can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

Tell your doctor, pharmacist or nurse if the following side effects become bothersome:

*Frequent side effects:*

- headache
- drowsiness
- dizziness

- nausea

*Less frequent side effects:*

- difficulty sleeping, sleeping disorders or nightmares and excessive dreaming
- nervousness
- sinusitis, cold or flu
- indigestion
- menstrual cramps
- tiredness

*Frequency unknown:*

- rapid heartbeat, heart skipping a beat or fluttering.

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. 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 Pollofex.

### **5. How to store Pollofex**

Store all medicines out of reach of children.

Store in the original pack at or below 25 °C. Protect from light. Keep the blisters in the carton until required for use.

### **6. Contents of the pack and other information**

#### **What Pollofex contains**

The active substance is fexofenadine hydrochloride.

Pollofex 120 contains 120 mg fexofenadine hydrochloride per film-coated tablet.

Pollofex 180 contains 180 mg fexofenadine hydrochloride per film-coated tablet.

The other ingredients are lactose monohydrate, hydroxypropyl cellulose, magnesium stearate and maize starch.

The tablet coating (Opadry Pink 03B54819) consists of hypromellose (6cP), iron oxide yellow (E172), iron oxide red (E172), macrogol 400 and titanium dioxide (E171).

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

Pollofex 120: Peach colour, film-coated, capsule-shaped tablets, plain on both sides, thickness of approximately 4,2 mm.

Pollofex 180: Peach colour, film-coated, capsule-shaped tablets, plain on both sides, thickness of approximately 5,4 mm.

Pollofex tablets are packed into white opaque PVC/PVDC/Alu blister strips consisting of 10 tablets, the blisters are packed into cartons with pack sizes of 30 tablets, or the tablets are packed into white to slightly yellow polypropylene containers with LDPE lid with pack sizes of 30 tablets. Not all pack types are always marketed.

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

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### **This leaflet was last revised on**

**Biotech Laboratories (Pty) Ltd**

Pollofex120 & 180 (A40/5.7.1/0590/1)

Each film-coated tablet contains 120 mg or 180 mg  
fexofenadine hydrochloride, respectively

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Approved Patient Information Leaflet

eCTD – 0000 - Baseline

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Pollofex 120: A40/5.7.1/0590

Pollofex 180: A40/5.7.1/0591