

# POLLOFEX

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S1

POLLOFEX 120 (120,0 mg film-coated tablets)  
POLLOFEX 180 (180,0 mg film-coated tablets)  
Fexofenadine hydrochloride  
POLLOFEX 120 contains sugar (156,0 mg lactose monohydrate)  
POLLOFEX 180 contains sugar (234,0 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 healthcare 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, Fexofenadine Biotech 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 healthcare 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 POLLOFEX 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 healthcare 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 overdose, 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 healthcare 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 120,0 mg fexofenadine hydrochloride per film-coated tablet.

POLLOFEX 180 contains 180,0 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 10 and 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

Biotech Laboratories (Pty) Ltd  
Ground Floor, Block K West, Central Park  
400 16<sup>th</sup> Road, Randjespark, Midrand  
South Africa, 1685  
Tel: +27 11 848 3050

#### This leaflet was last revised on

31 July 2022

#### Registration number

POLLOFEX 120: A40/5.7.1/0590

POLLOFEX 180: A40/5.7.1/0591

# POLLOFEX

## PASIËNTINLIGTINGSBLAD

### SKEDULERINGSSTATUS:

S1

POLLOFEX 120 (120,0 mg filmbedekte tablette)  
POLLOFEX 180 (180,0 mg filmbedekte tablette)  
Feksofenadienhidrochloried  
POLLOFEX 120 bevat suiker (156,0 mg laktosemonohidraat)  
POLLOFEX 180 bevat suiker (234,0 mg laktosemonohidraat)

### Lees die hele pamflet noukeurig deur, want dit bevat belangrike inligting vir jou

POLLOFEX is beskikbaar sonder 'n dokter se voorskrif, vir jou om 'n ligte siekte te behandel. Nietemin moet jy POLLOFEX steeds versigtig gebruik om die beste resultate daaruit te kry.

- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Moenie POLLOFEX met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.

### Wat is in hierdie pamflet

1. Wat POLLOFEX is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy POLLOFEX neem
3. Hoe om POLLOFEX te neem
4. Moontlike nuwe-effekte
5. Hoe om POLLOFEX te bewaar
6. Inhoud van die pakkie en ander inligting

### 1. Wat POLLOFEX is en waarvoor dit gebruik word

POLLOFEX-tablette behoort aan 'n groep medisyne wat antihistamiene genoem word.

POLLOFEX 120 word gebruik om simptome van seisoenale allergiese rinitis (hooikoors) te behandel en te verlig.

POLLOFEX 180 word gebruik om simptome van chroniese idiopatiese urtikaria (chroniese velbulte) te behandel en te verlig.

### 2. Wat jy moet weet voordat jy POLLOFEX neem

#### Moet nie POLLOFEX neem nie:

- as jy hipersensitief (allergies) is vir feksofenadienhidrochloried of enige van die ander bestanddele van POLLOFEX (gelys in afdeling 6).
- as jy swanger is of borsvoed.
- POLLOFEX moet nie aan kinders onder die ouderdom van 12 jaar gegee word nie, aangesien die veiligheid en doeltreffendheid nie bestudeer is nie.

### Waarskuwings en voorsorgmaatreëls

#### Wees veral versigtig met POLLOFEX:

- as jy bejaard is
- as jy lewerprobleme het
- as jy nierprobleme het
- as jy 'n geskiedenis van hartsiekte of voortgesette hartsiekte het, kan POLLOFEX bykomende nuwe-effekte veroorsaak (sien Nuwe-effekte)

### Kinders en adolessente

Moenie POLLOFEX aan kinders onder die ouderdom van 12 jaar gee nie, aangesien die veiligheid en doeltreffendheid nie bestudeer is nie.

### Ander medisyne en POLLOFEX

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

### Die volgende medisyne kan die vlakke van POLLOFEX in jou bloed verhoog:

- eritromisien ('n antibiotika)
- ketokonasool ('n medisyne wat gebruik word om swaminfeksies te behandel).

### Die volgende medisyne kan die vlakke van POLLOFEX in jou bloed verlaag

- teensuurmiddels, aangesien dit die opname van POLLOFEX uit jou ingewande kan verminder.

Dit is raadsaam om POLLOFEX en teensuurmiddels wat aluminium en magnesiumhidroksied bevat ten minste 2 uur uitmekaar te neem.

Geen interaksie tussen POLLOFEX en die medisyne omeprasool is waargeneem nie.

### POLLOFEX met kos en drank

Jy kan lomerig of slaperig word as jy alkohol drink terwyl jy POLLOFEX neem.

### Swangerskap en borsvoeding

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.

Moenie POLLOFEX neem as jy swanger is of as jy jou baba borsvoed nie.

### Bestuur en gebruik van masjinerie

Dit is onwaarskynlik dat POLLOFEX jou vermoë om te bestuur of masjinerie te bestuur, sal beïnvloed. 'n Klein aantal individue kan sedasie ervaar. Die gelyktydige inname van alkohol of medisyne genoem sentrale senuweestelsel-depressante kan lei tot lomerigheid en sedasie. Dit is nie altyd moontlik om te voorspel tot watter mate POLLOFEX met jou daaglikse aktiwiteite kan inmeng nie. Jy moet verseker dat jy nie 'n voertuig bestuur of masjinerie gebruik totdat jy bewus is van die mate waarin POLLOFEX jou beïnvloed nie.

### POLLOFEX bevat laktose

As jou dokter jou ingelig het dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy POLLOFEX neem.

### 3. Hoe om POLLOFEX te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem POLLOFEX altyd presies soos beskryf in hierdie pamflet of soos jou dokter, apteker of verpleegster vir jou gesê het. Raadpleeg met jou dokter, apteker of verpleegster as jy nie seker is nie.

*Die gewone dosis vir volwassenes en kinders van 12 jaar en ouer is:*

POLLOFEX 120: Die gewone dosis is een 120 mg tablet een keer per dag.  
POLLOFEX 180: Die gewone dosis is een 180 mg tablet een keer per dag.

As jy vellaagde nierfunksie het, is die aanbevole aanvangsdosis 60 mg een keer per dag.

Neem jou tablet mondelings. Sluk jou tablet met bietjie water, moenie die tablet kou nie.

As jy die indruk het dat die effek van POLLOFEX te sterk of te swak is, vertel jou dokter, apteker of verpleegster.

### As jy meer POLLOFEX neem as wat jy moet

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Simptome van oordosering kan duiseligheid, lomerigheid of 'n droë mond insluit.

### As jy vergeet om POLLOFEX te neem

Moenie 'n dubbeldosis neem om vergeet individuele dosisse in te haal nie.

### As jy ophou om POLLOFEX te neem

Die simptome van jou allergie kan terugkeer as jy ophou om POLLOFEX te neem

### 4. Moontlike nuwe-effekte

POLLOFEX kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir POLLOFEX aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg of as u enige nadelige effekte ervaar terwyl u POLLOFEX gebruik, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

### As enige van die volgende gebeur, hou op om POLLOFEX te neem en lig jou dokter dadelik in of gaan na die ongevallen-afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal
- uitslag of jeuk
- flou word.

Hierdie is alles baie ernstige nuwe-effekte. As jy dit ervaar, het jy dalk 'n ernstige reaksie op POLLOFEX gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

### Vertel jou dokter, apteker of verpleegster as die volgende nuwe-effekte lastig raak:

*Algemene nuwe-effekte:*

- hoofpyn
- lomerigheid
- duiseligheid
- naarheid

*Minder algemene nuwe-effekte:*

- Probleme om te slaap, slaapversteurings of nagmerries en oormatige droom
- senuweeagtigheid
- sinusitis, verkoue of griep
- slegte spysvertering
- menstruasie krampe
- moegheid

*Voorkoms onbekend:*

- winnige hartklop, hart wat 'n klop oorslaan of fladder.

Indien u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

### Aanmelding van nuwe-effekte

As jy nuwe-effekte kry, praat met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van POLLOFEX te verskaf.

### 5. Hoe om POLLOFEX te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar in die oorspronklike verpakking teen of benede 25 °C.

Beskermt teen lig.

Hou die stulpstrokke in die karton totdat dit benodig word vir gebruik.

### 6. Inhoud van die pakkie en ander inligting

#### Wat POLLOFEX bevat

Die aktiewe bestanddeel is feksofenadienhidrochloried.

POLLOFEX 120 bevat 120,0 mg feksofenadienhidrochloried per filmbedekte tablet.

POLLOFEX 180 bevat 180,0 mg feksofenadienhidrochloried per filmbedekte tablet.

Die ander bestanddele is laktosemonohidraat, hidroksiopropiëlsellulose, magnesiumstearaat en mieliëstysel. Die tabletbekleding (Opadry Pink 03B54819) bestaan uit hipromellose (6cP), ysteroksied geel (E172), ysteroksied rooi (E172), makrogol 400 en titaandioksied (E171).

#### Hoe POLLOFEX lyk en die inhoud van die verpakking

POLLOFEX 120: Perskekleur, filmbedekte, kapsulevormige tablette, glad aan beide kante, dikte van ongeveer 4,2 mm.

POLLOFEX 180: Perskekleur, filmbedekte, kapsulevormige tablette, glad aan beide kante, dikte van ongeveer 5,4 mm.

POLLOFEX tablette word verpak in wit ondeursigtige PVC/PVDC/Alu stulpstrokke wat uit 10 tablette bestaan, die stulpstrokke word verpak in kartonne met pakgroottes van 10 of 30 tablette, of die tablette word verpak in wit tot effens geel polipropileenhouers met LDPE-deksel met pakgroottes van 30 tablette. Nie alle verpakkinge word altyd bemark nie.

#### Houer van die Sertifikaat van Registrasie

Biotech Laboratories (Edms) Bpk  
Blok K Wes, Central Park  
400 16<sup>de</sup> Weg, Randjespark, Midrand  
Suid-Afrika  
1685  
Tel: +27 11 848 3050

#### Hierdie pamflet is laas hersien op

31 Julie 2022

#### Registrasie Nommer

POLLOFEX 120: A40/5.7.1/0590

POLLOFEX 180: A40/5.7.1/0591