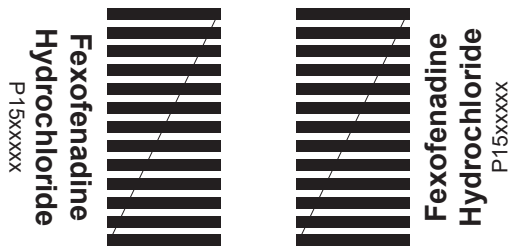
Pharmacode position may change as per Supplier's m/c requirement &additional small pharma code may appear on the front / back panel



Package leaflet: Information for the user

Fexofenadine Hydrochloride 180 mg Film-Coated Tablets

fexofenadine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Fexofenadine Hydrochloride is and what it is used for

Fexofenadine Hydrochloride 180 mg Film-Coated Tablets contains fexofenadine hydrochloride, which is a non-drowsy antihistamine.

Fexofenadine Hydrochloride 180 mg Film-Coated Tablets is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long-term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling and rashes.

2. What you need to know before you take Fexofenadine Hydrochloride

Do not use Fexofenadine Hydrochloride:
- If you are allergic to fexofenadine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Fexofenadine hydrochloride if:
- you have problems with your liver or kidneys
- you have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat
- you are elderly

If any of these apply to you, or if you are not sure, tell your doctor before taking Fexofenadine hydrochloride.

Children and adolescents
Fexofenadine Hydrochloride 180 mg Film-Coated Tablets is not recommended for children less than 12 years of age.

In children from 6 to 11 years of age: fexofenadine hydrochloride 30 mg tablet is the appropriate formulation for administration and dosing in this population.

Other medicines and Fexofenadine Hydrochloride
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking apalutamide (a medicine to treat prostate cancer), as the effect of fexofenadine may be decreased.

It is especially important to talk to your doctor before you take fexofenadine if you are also taking any of the following medicines:
- an antibiotic used to treat certain bacterial infections (erythromycin).
- an antifungal used to treat fungal infections (ketoconazole).

These medicines increase the amount of fexofenadine absorbed.

Indigestion remedies containing aluminium and magnesium may affect the action of fexofenadine by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take Fexofenadine Hydrochloride and your indigestion remedy.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take fexofenadine hydrochloride if you are pregnant, unless recommended by your doctor.

Fexofenadine Hydrochloride is not recommended during breast-feeding.

Driving and using machines
Fexofenadine Hydrochloride is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

Fexofenadine Hydrochloride 180 mg Film-Coated Tablets contain Sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet that is to say essentially 'sodium-free'.

Fexofenadine Hydrochloride 180 mg Film-Coated Tablets contain Lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Fexofenadine Hydrochloride

Dosage
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For adults and children aged 12 years and over
The recommended dose is one tablet (180 mg) daily. Take your tablet with water before a meal. This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours.

If you take more Fexofenadine Hydrochloride than you should
If you take too many tablets, contact your doctor or pharmacist or the nearest hospital emergency department immediately. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

If you forget to use Fexofenadine Hydrochloride
Do not take a double dose to make up for a forgotten tablet. Take the next dose at the usual time as planned.

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If you stop using Fexofenadine Hydrochloride
If you stop taking Fexofenadine Hydrochloride your symptoms may return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking Fexofenadine Hydrochloride if you experience:
- swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patient who did not receive the drug (placebo).

Common side effects (may affect up to 1 in 10 people):
- headache
- drowsiness
- feeling sick (nausea)
- dizziness

Uncommon side effects (may affect up to 1 in 100 people):
- tiredness
- sleepiness

Additional side effects (frequency not known: cannot be estimated from the available data) which may occur are:
- difficulty sleeping (insomnia)
- sleeping disorders
- bad dreams
- nervousness
- fast or irregular heartbeat
- diarrhoea
- skin rash and itching
- hives
- serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness, and difficulty breathing
- blurred vision

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Fexofenadine Hydrochloride

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fexofenadine Hydrochloride Film-Coated Tablets contain
- The active substance is fexofenadine hydrochloride.

Each film-coated tablet contains 180 mg fexofenadine hydrochloride, which is equivalent to 168 mg of fexofenadine.

- The other ingredients are:
Tablet core: Croscarmellose sodium, lactose, lactose monohydrate, maize starch, silica, colloidal anhydrous, starch, pregelatinised, stearic acid
Tablet coating: Iron oxide red (E172), iron oxide yellow (E172), hypromellose type 2910 6 mPas (E464), macrogol 400 (E1521), titanium dioxide (E171)

What Fexofenadine Hydrochloride 180 mg Film-Coated Tablets look like and contents of the pack

Film-coated tablet
Peach-coloured, capsule shaped, bevel edge, biconvex film-coated tablets debossed with “FE” on one side and “180” on other side.
Fexofenadine Hydrochloride 180 mg Film-Coated Tablets are available in blister and HDPE bottle packs.

Pack sizes:
Blister packs: 7, 15, 20, 30, 50, 60 and 100 film-coated tablets
HDPE pack: 500 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Milpharm Limited
1 Roundwood Avenue,
Stockley Park,
Uxbridge,
UB11 1AF
United Kingdom

Manufacturer
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

Generis Farmaceutica, S.A.,
Rua Joao De Deus, N 19, Venda Nova,
Amadora, 2700-487, Portugal.

Milpharm Limited
1 Roundwood Avenue,
Stockley Park,
Uxbridge,
UB11 1AF
United Kingdom

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