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Front

Place for Pharmacode

Package leaflet: Information for the user

Fexofenadine hydrochloride 120 mg film-coated tablets
Fexofenadine hydrochloride 180 mg film-coated tablets
(Fexofenadine hydrochloride)

The full name of your medicine is Fexofenadine hydrochloride 120 mg film-coated tablets or Fexofenadine hydrochloride 180 mg film-coated tablets. It is referred to as Fexofenadine hydrochloride tablets in the rest of this leaflet.

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

- What Fexofenadine hydrochloride tablets are and what they are used for
- What you need to know before you take Fexofenadine hydrochloride tablets
- How to take Fexofenadine hydrochloride tablets
- Possible side effects
- How to store Fexofenadine hydrochloride tablets
- Contents of the pack and other information

1. What Fexofenadine hydrochloride tablets are and what they are used for

Fexofenadine hydrochloride tablets contain fexofenadine hydrochloride, which is a non-drowsy antihistamine.

Fexofenadine hydrochloride 120 mg tablets are 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.

Fexofenadine hydrochloride 180 mg tablets are 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 tablets

Do not take Fexofenadine hydrochloride tablets

- 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 tablets 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 tablets.

Other medicines and Fexofenadine hydrochloride tablets

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.

Indigestion remedies containing aluminium and magnesium may affect the action of Fexofenadine hydrochloride tablets 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 tablets and your indigestion remedy.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take Fexofenadine hydrochloride tablets if you are pregnant, unless necessary.

Fexofenadine hydrochloride tablets is not recommended during breast-feeding.

Driving and using machines

Fexofenadine hydrochloride tablets 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 tablets contains sodium

120mg - This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially sodium free.
180mg - This medicine contains 30mg sodium per tablet.

3. How to take Fexofenadine hydrochloride tablets

Always take 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 (120 mg or 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 tablets than you should

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately.

Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

Back

If you forget to take Fexofenadine hydrochloride tablets
Do not take a double dose to make up for a forgotten tablet.

Take the next dose at the usual time as prescribed by your doctor.

If you stop taking Fexofenadine hydrochloride tablets
Tell your doctor if you want to stop taking Fexofenadine hydrochloride tablets before you have finished your course of treatment.

If you stop taking Fexofenadine hydrochloride tablets earlier than planned, 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 tablets 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.
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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 heart beat	• 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.	

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 tablets

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 carton after EXP. The expiry date refers to the last day of that month.

This medicine 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 tablets contain

For 120mg:

- The active substance is fexofenadine hydrochloride. Each tablet contains 120 mg of fexofenadine hydrochloride.
- The other ingredients are:
 - Tablet core:** microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, povidone (K-30), colloidal anhydrous silica, magnesium stearate.
 - Film coating:** hydroxyl propyl methyl cellulose, polyethylene glycol, titanium dioxide (E171), iron oxide red (E172) and iron oxide yellow (E172).

For 180mg:

- The active substance is fexofenadine hydrochloride. Each tablet contains 180 mg of fexofenadine hydrochloride.
- The other ingredients are:
 - Tablet core:** microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, povidone (K-30), colloidal anhydrous silica, magnesium stearate.
 - Film coating:** hydroxyl propyl methyl cellulose, polyethylene glycol, titanium dioxide (E171), iron oxide red (E172) and iron oxide yellow (E172).

What Fexofenadine hydrochloride tablets look like and contents of the pack

For 120mg:
Peach coloured, modified capsule shaped film coated tablets embossed with "120" on one side and plain on the other side

For 180mg:
Peach coloured, modified capsule shaped film coated tablets having plain surface on both sides

Fexofenadine hydrochloride tablets are presented in blister packs. Each tablet is blistered.

Fexofenadine hydrochloride tablets are available in packs of 2 (sample only), 7, 10, 15, 20, 30, 50, 100 and 200 (as 10x20) tablets per package.

Not all pack sizes are marketed.

Marketing Authorisation Holder:
Somex Pharma, Ilford, Essex, IG3 8BS. UK

Manufacturer:
Somex Pharma, Ilford, Essex, IG3 8RA. UK

This leaflet was last revised in April 2024

Other sources of information:

To request a copy of this leaflet in braille or large print please call: 020 8590 9399 (UK Only)

ITEM CODE

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