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PACKAGE LEAFLET: INFORMATION FOR THE USER

Fexofenadine hydrochloride 120 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 120 mg Film-Coated Tablets are and what they are used for
2. What you need to know before you take Fexofenadine hydrochloride 120 mg Film-Coated Tablets
3. How to take Fexofenadine hydrochloride 120 mg Film-Coated Tablets
4. Possible side effects
5. How to store Fexofenadine hydrochloride 120 mg Film-Coated Tablets
6. Contents of the pack and other information

1. WHAT FEXOFENADINE HYDROCHLORIDE 120 MG FILM-COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Fexofenadine hydrochloride 120 mg Film-Coated Tablets contain fexofenadine hydrochloride, which is an antihistamine.

Fexofenadine hydrochloride 120 mg Film-Coated 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 120 mg Film-Coated Tablets will also be referred to in this leaflet as Fexofenadine Tablets.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FEXOFENADINE HYDROCHLORIDE 120 MG FILM-COATED TABLETS

Do not take Fexofenadine 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 Tablets if you:

- have problems with your liver or kidneys
- have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat are elderly.

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

Other medicines and Fexofenadine 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 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 Tablets and your indigestion remedy.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Do not take Fexofenadine hydrochloride 120 mg Film-Coated Tablets if you are pregnant, unless necessary. Fexofenadine Tablets are not recommended during breastfeeding.

Driving and using machines

Fexofenadine ablets are 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 Tablets also contain Allura Red AC Lake, which may cause allergic reactions.

For a full list of ingredients, please see 'Contents of the pack and other information'.

3. HOW TO TAKE FEXOFENADINE HYDROCHLORIDE 120 MG FILM-COATED 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) daily. Take your tablet with water before a meal. This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours.

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If you take more Fexofenadine 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.

If you forget to take Fexofenadine 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 Tablets

Tell your doctor if you want to stop taking Fexofenadine Tablets before you have finished your course of treatment. If you stop taking Fexofenadine 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 Tablets if you experience:

- swelling of the face, lips, tongue or throat, flushing, chest tightness and difficulty breathing, as these may be signs of a serious allergic reaction.

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
- blurred vision
- fast or irregular heart beat
- diarrhoea
- skin rash and itching
- hives.

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 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 120 MG FILM-COATED 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 Tablets contain

The active substance is fexofenadine hydrochloride. Each Film-Coated tablet contains 120mg of fexofenadine hydrochloride: equivalent to 112mg of fexofenadine.
The other ingredients (excipients) are:
Tablet core: powdered cellulose, mannitol (E421), maize starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.
Tablet coating: opadry pink film-coating mixture containing hypromellose (E464), titanium dioxide (E171), macrogol 400, allura red AC lake (FD&C Red #40) (E129), and iron oxide, black (E172)

What Fexofenadine hydrochloride 120 mg Film-Coated Tablets look like and contents of the pack

Fexofenadine hydrochloride 120 mg Film-Coated Tablets are pink coloured, oval, tablets marked with "FXF" on one side and "120" on the other side.
Fexofenadine Tablets are packed in blister strips packaged in cartons.
The cartons contain 20 or 30 Tablets. Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer

Dr. Reddy's Laboratories (UK) Ltd,
410 Cambridge Science Park, Milton Road, Cambridge, CB4 0PE, United Kingdom
Fexofenadine hydrochloride 120 mg Film-Coated Tablets: PL08553/0273

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Submission

Brand: DR Reddy's
Country: UK
Product Name: Fexofenadine Hydrochloride
Strength: 120 mg
Form: Film-coated tablets
Component: PIL
Pack Size: Various
Date Created: 09 Nov2020
Date Modified: 22 Feb 23x

Project: CC1000103630

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Previous Material Number: 15009082

Commercial

DR No: Xxxxxxx
DRUGS Code: N/A
Material Code: N/A
Third Party Material Code: N/A
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Barcode Number: N/A
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