Package leaflet: Information for the patient

Fexofenadine Cipla 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, pharmacist or nurse.
- 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 Cipla is and what it is used for

Fexofenadine Cipla contains fexofenadine hydrochloride, which is an antihistamine.

Fexofenadine Cipla 120 mg is 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.

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

Do not take Fexofenadine Cipla
- 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, pharmacist or nurse before taking Fexofenadine Cipla if
- you have problems with the way your liver or kidneys work;
- you have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat;
- you are elderly

Children and adolescents
Fexofenadine Cipla 120 mg film-coated tablet is not recommended in children and adolescents below 12 years of age.

Other medicines and Fexofenadine Cipla
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 Cipla, by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take Fexofenadine Cipla 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 Cipla if you are pregnant, unless necessary.

Fexofenadine Cipla is not recommended during breast-feeding.

Driving and using machines
Fexofenadine Cipla 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 Cipla contains sodium

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

3. How to take Fexofenadine Cipla

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 adolescents 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.

Use in children and adolescents
Fexofenadine Cipla 120 mg film-coated tablet is not recommended in children and adolescents below 12 years of age.

If you take more Fexofenadine Cipla 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 Cipla
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 Cipla
Tell your doctor if you want to stop taking Fexofenadine Cipla before you have finished your course of treatment.

If you stop taking Fexofenadine Cipla 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 Cipla 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 side effects have also been reported:

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

Not known (frequency cannot be estimated from the available data)**:**
- 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.
- Blurred vision

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 (see details below)**.** By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Fexofenadine Cipla

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/label/ blister 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 Cipla contains:

- The active substance is fexofenadine hydrochloride. Each film coated tablet contains 120 mg of fexofenadine hydrochloride
- The other ingredients are:
  - Tablet core: microcrystalline cellulose , maize starch, croscarmellose sodium, povidone, magnesium stearate
  - Film coating: hypromellose, titanium dioxide (E171), macrogol, iron oxide yellow (E172), iron oxide red (E172)

What Fexofenadine Cipla looks like and contents of the pack

Fexofenadine Cipla 120 mg film-coated tablets are peach coloured, oblong, biconvex, film-coated tablets plain on both sides. Dimensions: 15.00 mm x 6.5 mm

PVC/PVDC/Al blisters, packaged into cardboard boxes. 7, 10, 15, 20, 30, 50, 100 and 200 (as 10x20) tablets per package.

Not all packs sizes may be marketed

This medicinal product is authorised in the Member States of the EEA under the following names

Sweden: Fexofenadin Cipla 120 mg filmdragerade tabletter
Germany: Fexofenadinhydrochlorid Cipla 120 mg Filmtabletten
Denmark: Fexofenadin "Cipla", filmovertrukne tabletter 120 mg
Spain: Fexofenadina Cipla 120 mg Comprimido recubierto con película
France: FEXOFENADINE CIPLA 120 mg, comprimé pelliculé
Finland: Fexorin
Croatia: Feksofenadinklorid Cipla 120 mg filmom obložene tablete
Norway: Feksofenadin Cipla 120 mg filmdrasjerte tablette
Poland: Fexofenadine hydrochloride Cipla, 120 mg, tabletki powlekane

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

For – SE, DE, ES, FR, DK, PL, NO, HR

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