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PACKAGE LEAFLET: INFORMATION FOR THE USER



Read all of this leaflet carefully before you start using 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 experience any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet, (see section 4).

In this leaflet:

1. What Pirilieve Hayfever Relief 120 mg film-coated tablets are and what they are used for
2. What you need to know before you take Pirilieve Hayfever Relief 120 mg film-coated tablets
3. How to take Pirilieve Hayfever Relief 120 mg film-coated tablets
4. Possible side effects of Pirilieve Hayfever Relief 120 mg film-coated tablets
5. How to store Pirilieve Hayfever Relief 120 mg film-coated tablets
6. Contents of the pack and other information

1. WHAT PIRILIEVE HAYFEVER RELIEF 120 MG FILM-COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Pirilieve Hayfever Relief 120 mg film-coated tablets contain Fexofenadine hydrochloride which is an antihistamine.

Pirilieve Hayfever Relief 120 mg film-coated tablets are used in adults and adolescents of 12 years of age and older to relieve the symptoms of hay fever (seasonal allergic rhinitis) such as sneezing, itchy, running or blocked nose and itchy, red and watery eye.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PIRILIEVE HAYFEVER RELIEF 120 MG FILM-COATED TABLETS

Do not take Pirilieve Hayfever Relief 120 mg film-coated tablets:

- if you are allergic to fexofenadine hydrochloride or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking Pirilieve Hayfever Relief 120 mg film-coated 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 Pirilieve Hayfever Relief 120 mg film-coated tablets.

Other medicines and Pirilieve Hayfever Relief 120 mg film-coated 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 Pirilieve Hayfever Relief 120 mg film-coated tablets by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take Pirilieve Hayfever Relief 120 mg film-coated tablets and your indigestion remedy

Pregnancy and breast-feeding

Pirilieve Hayfever Relief 120 mg film-coated tablets should not be taken during pregnancy and whilst breast-feeding unless advised by a doctor.

Driving and using machines

Pirilieve Hayfever Relief 120 mg film-coated 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.

Pirilieve Hayfever Relief 120 mg film-coated tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per 120 mg of fexofenadine hydrochloride film-coated tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE PIRILIEVE HAYFEVER RELIEF 120 MG FILM-COATED TABLETS

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist 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. Pirilieve Hayfever Relief 120 mg film-coated tablets is not recommended for children under 12 years of age.

If you take more Pirilieve Hayfever Relief 120 mg film-coated 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 Pirilieve Hayfever Relief 120 mg film-coated tablets

Do not take a double dose to make up for a forgotten tablet. Take the next dose at the usual time.

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 Pirilieve Hayfever Relief 120 mg film-coated 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

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 heart beat
- diarrhea
- 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 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 PIRILIEVE HAYFEVER RELIEF 120 MG FILM-COATED TABLETS

Keep this medicine out of 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 medicinal product does not require any special storage conditions. 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pirilieve Hayfever Relief 120 mg film-coated tablets contain

- The active substance is fexofenadine hydrochloride.

Each Pirilieve Hayfever Relief 120 mg film-coated tablets contain 120 mg of fexofenadine hydrochloride

- The other ingredients are:
 - *Tablet core:* microcrystalline cellulose, croscarmellose sodium, maize starch, povidone, magnesium stearate.
 - *Tablet coat:* hypromellose (E464), titanium dioxide (E171), macrogol 400, macrogol 4000, iron oxide yellow (E172) and iron oxide red (E172).

What Pirilieve Hayfever Relief 120 mg film-coated tablets look like and contents of the pack

Pirilieve Hayfever Relief 120 mg film-coated tablets are peach coloured, oblong, film-coated tablets, plain on both sides.

Pirilieve Hayfever Relief 120 mg film-coated tablets come in packs of 2, 7, 10, 15, 20, 30 tablets; not all pack sizes may be marketed.

Marketing Authorisation Holder

Chanelle Medical Unlimited Company, Dublin Road, Loughrea, Co. Galway, Ireland

Manufacturer

Chanelle Medical Unlimited Company, Dublin Road, Loughrea, Co. Galway, Ireland

Distributor:

Haleon UK Trading Limited, The Heights, Weybridge, KT13 0NY, U.K.

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