

Package leaflet: Information for the user

TREATHAY 120mg film coated tablets

Fexofenadine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after taking TREATHAY.

What is in this leaflet

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

1. What TREATHAY is and what they are used for

The active ingredient in your tablets is fexofenadine hydrochloride, which belongs to a group of medicines called antihistamines. It can be used in adults and adolescents of 12 years and older to relieve the symptoms of hay fever (seasonal allergic rhinitis), such as sneezing, itchy, runny or blocked nose and red, itchy and watery eyes.

TREATHAY is not suitable for children under 12 years of age.

2. What you need to know before you take TREATHAY

Do not take TREATHAY

- 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 TREATHAY if you:

- have problems with your liver or kidneys
- are elderly
- have or ever had heart problems, as fexofenadine, like other antihistamines may cause your heart to beat faster (tachycardia) or you feel your heart beating (palpitations).

If any of these apply to you, or if you are not sure, tell your doctor or pharmacist before taking this medicine.

Other medicines and TREATHAY

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.

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 TREATHAY by lowering the amount of medicinal product absorbed.

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

TREATHAY with food and drink

TREATHAY should be taken before meals with water.

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.

TREATHAY should not be taken during pregnancy and whilst breast-feeding unless advised by a doctor.

Driving and using machines

TREATHAY 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.

TREATHAY contain sodium

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

3. How to take TREATHAY

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.

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.

If symptoms persist or worsen, stop use and consult your doctor or pharmacist.

Do not take more than one tablet in 24 hours.

TREATHAY is not recommended for children under 12 years of age.

If you take more TREATHAY than you should

If you have accidentally taken more than this leaflet recommended, contact your nearest hospital emergency department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you.

The most common signs of overdose are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take TREATHAY

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.

If you get any of the following symptoms after taking these tablets you should contact your doctor or pharmacist immediately as these may be signs of a serious allergic reaction:

- Swelling of the face, lips, tongue or throat and difficulty breathing.

The following side effects have also been reported:

Common (may affect up to 1 in 10 people):

- headache
- drowsiness
- feeling sick (nausea)
- dizziness

Uncommon (may affect up to 1 in 100 people):

- tiredness or 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 reaction which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness
- 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 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 TREATHAY

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

Do not take this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of the month.

Store in the original package.

This medicinal product does not require any special temperature 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 TREATHAY contains

The active substance is fexofenadine hydrochloride. Each film-coated tablet contains 120 mg of fexofenadine hydrochloride, which is equivalent to 112 mg of fexofenadine

The other ingredients are:-

- *Tablet core*: Microcrystalline cellulose, maize starch, magnesium stearate, croscarmellose sodium, povidone.
- *Film coating*: Hypromellose (E464), macrogol (PEG 400), macrogol (PEG 4000), titanium dioxide (E171), iron oxide yellow (E172) and iron oxide red (E172).

What TREATHAY looks like and the contents of the pack:

TREATHAY 120 mg film-coated tablet are peach coloured, oblong, biconvex, film coated tablets.

TREATHAY is available in PVC/PVDC/Alu blister packs of 7, 10, 14, 15, 20, 21, 28 or 30 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

Marketing Authorisation Holder

CIPLA (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom

Manufacturer

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