

Package leaflet: Information for the user

# Treathay 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.**

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 120 mg film-coated tablets.

## What is in this leaflet

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

## 1. What Treathay 120 mg film-coated tablets are 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 120 mg film-coated tablets are not suitable for children under 12 years of age.

## 2. What you need to know before you take Treathay 120 mg film-coated tablets

### Do not take Treathay 120 mg film-coated 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 Treathay 120 mg film-coated tablets if you:

- have problems with your liver or kidneys
- are elderly
- have or have 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 120 mg film-coated tablets

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 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 Treathay 120 mg film-coated tablets and your indigestion remedy.

## Treathay 120 mg film-coated tablets with food and drink

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

## Driving and using machines

Treathay 120 mg film-coated tablets 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.

## Treathay 120 mg film-coated tablets 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 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.

### 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 120 mg film-coated tablets is not recommended for children under 12 years of age.**

Further information overleaf

## If you take more Treathay 120 mg film-coated tablets 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 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.

**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 heartbeat
- 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](http://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 120 mg film-coated tablets

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 120 mg film-coated tablets contain

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).

### Treathay 120 mg film-coated tablets looks like and the contents of the pack:

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

Treathay 120 mg film-coated tablets are 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

Galpharm Healthcare Ltd., Wrafton, Braunton, EX33 2DL, United Kingdom

#### Manufacturer

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

Cipla Europe NV, De Keyserlei 58-60, Box-19, 2018 Antwerp, Belgium

PL 16028/0190

This leaflet was last revised in 04/2023.

G4L00H9J2

JOB INFORMATION		JOB SPECIFICATION	
Product Name: Treathay 120 mg film-coated tablets	Project Name: 000391_Retailer Own Label Fexofenadine	Dimensions: 190 x 230mm	Supplier: Cipla - Ptg 2
Customer: Galpharm	HUB No.: 14395	Profile No.: L6010	Printer: TBC
Market: UK	Component No.: G4L00H9J2	Pharmacode: N/A	Print Process: Litho
Component: Leaflet	Customer Code: N/A	EAN Code: N/A	Substrate: White Paper
Pack Size: 10, 30	Supplier Code: TBC	<b>MAIN BODY TEXT</b>	
Licence No.: PL 16028/0190	Export Code: N/A	Font Type: Helvetica Neue Light	Font Size: 9pt
<b>COLOURS</b>			
Print Colours: BLACK		Non-print Colours: CUTTER	