

Telfast® 120mg Tablets

(fexofenadine hydrochloride)

1173
02.05.17[9]

PATIENT INFORMATION LEAFLET

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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (see section 4.)

Your medicine is available as the above name but will be referred to as Telfast throughout this leaflet.

What is in this leaflet:

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

1. WHAT TELFAST IS AND WHAT IT IS USED FOR

Telfast is an antihistamine.

It 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 TELFAST

Do not take Telfast:

- 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 Telfast 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 Telfast.

Other medicines and Telfast

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

Indigestion remedies containing aluminium and magnesium may affect the action of Telfast, by lowering the amount of medicinal product absorbed.

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

Telfast is not recommended during breast-feeding.

Driving and using machines

Telfast 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.

3. HOW TO TAKE TELFAST

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.

If you take more Telfast 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 Telfast

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 Telfast

Tell your doctor if you want to stop taking Telfast before you have finished your course of treatment. If you stop taking Telfast 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 Telfast 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
- 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.

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.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE TELFAST

Keep out of the sight and reach of children.

Do not use Telfast 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 condition.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

If the tablets become discoloured or show any other sign of deterioration, seek the advice of your pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Telfast 120 mg contains

The active substance of Telfast is fexofenadine hydrochloride.

Each film-coated tablet contains 112mg of the active ingredient fexofenadine (as 120mg of fexofenadine hydrochloride).

The other ingredients are microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, magnesium stearate, hypromellose, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400 and iron oxide (E172).

What Telfast 120 mg looks like and contents of the pack

Telfast are peach, modified capsule shaped, film coated tablets marked **Q12** on one face and a scripted "e" on the other face.

Available in pack size of 30 tablets.

Manufacturer and Product Licence Holder

Manufactured by Sanofi-Synthelabo Ltd, Fawdon, UK.

Procured from within the EU by Product Licence holder

Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharma Ltd.

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