

Package Leaflet: Information for the user

Telfast® 30 mg film-coated tablets

Fexofenadine hydrochloride

sanofi

Read all of this leaflet carefully before your child starts 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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets 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 Telfast is and what it is used for
2. What you need to know before your child uses Telfast
3. How to use Telfast
4. Possible side effects
5. How to store Telfast
6. Content of the pack and other information

1. What Telfast is and what it is used for



Telfast contains fexofenadine hydrochloride, which is a non-drowsy antihistamine.

Telfast 30 mg is used in children 6 to 11 years old 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 your child uses Telfast



Do not use Telfast

- × if your child is 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 using Telfast if:

- ▲ if your child has liver or kidney problems
- ▲ if your child has or ever had heart disease, since this medicine may lead to a fast or irregular heart beat

If any of these apply to your child, or if you are not sure, always tell your doctor before giving Telfast to your child.



Other medicines and Telfast

Tell your doctor or pharmacist if your child is taking, has 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 Telfast, by lowering the amount of medicinal product absorbed.

It is recommended that 2 hours are left between the time that your child takes Telfast and the indigestion remedy.

Pregnancy and breast-feeding

This medicine is for use in children 6 – 11 years of age.

However, the following information should be noted regarding the safe use of this medicine.

Ask your doctor or pharmacist for advice before giving any medicine to your child.

Telfast should not be taken during pregnancy, unless necessary.

Telfast is not recommended during breast-feeding.



Driving and using machines

Telfast is unlikely to affect one's ability to drive or use machines. However, you should check that these tablets do not make your child feel sleepy or dizzy.

Do not let your child drive or use machines if they are affected.

Telfast contains sodium

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

3. How to use Telfast

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For children aged 6 to 11 years of age

The recommended dose is one tablet (30 mg) twice daily.

The tablet should be taken with water.

If you use more Telfast than you should

If your child takes too many tablets, contact your doctor or the nearest hospital emergency department immediately.

Symptoms of an overdose are dizziness, drowsiness, fatigue and dry mouth.

If you forget to use Telfast

Do not give a double dose to make up for a forgotten tablet.

Give the next dose at the usual time as prescribed by the doctor.

If you stop using Telfast

Tell your doctor if you want your child to stop taking Telfast before the course of treatment has finished.

If treatment with Telfast is stopped earlier than planned, the 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 treatment with Telfast if your child experiences:

- swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

In clinical trials in children 6 to 11 years of age, the most common side effect was headache.

The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patient who did not receive the drug (placebo).

In adults, the following side effects have 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.

Additional side effects (Not known: frequency 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.
- blurred vision

Reporting of side effects

If your child gets 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 Telfast

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 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 Telfast 30 mg film-coated tablets contains

The active substance is fexofenadine hydrochloride. Each tablet contains 30 mg of fexofenadine hydrochloride.

The other ingredients are:

- **Tablet core:** microcrystalline cellulose, pregelatinised starch, croscarmellose sodium, magnesium stearate.
- **Film coating:** hypromellose, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol, pink iron oxide (E172) blend and yellow iron oxide (E172) blend.

What Telfast 30 mg looks like and contents of the pack

Telfast 30 mg film coated tablets are round and peach coloured, marked with "03" on one side and a scripted "e" on the other.

Telfast is presented in blister packs. Each tablet is blistered.

Telfast is available in packs of 1, 2, 4, 8, 10, or 15 (sample only), 20, 30, 40, 50, 60, and 100 tablets per package.

Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Sanofi, 410 Thames Valley Park Drive
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Manufacturer:

Sanofi Winthrop Industrie,
30-36 Avenue Gustave Eiffel,
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This medicinal product is authorised in the Member states of the EEA under the following names:

Belgium: Telfast 30 mg filmomhulde tabletten

Denmark: Telfast, filmovertrukne tabletter 30 mg

Finland: Telfast 30 mg tabletti, kalvopäällysteinen

Iceland: Telfast 30 mg filmuhúðaðar töflur

Ireland: Telfast 30 mg film coated tablets

Italy: Telfast 30 mg compresse rivestite con film

Luxembourg: Telfast 30 mg filmomhulde tabletten

Norway: Telfast 30 mg filmdrasjerte tabletter

Poland: Telfast 30

Portugal: Telfast 30, comprimidos revestidos por película

United Kingdom: Telfast 30 mg film coated tablets

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