

Telfast®

Children's Elixir and 30 mg tablets

Fexofenadine hydrochloride

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Telfast. Please read the information carefully before giving your child Telfast.

This leaflet provides a summary of the information available, it does not contain all the available information.

It does not take the place of talking to your pharmacist or doctor, who have more detailed information.

If you have any questions about Telfast, or if your child experiences any problems while being given Telfast, speak to your pharmacist or doctor.

All medicines have benefits and risks, so please discuss these with your pharmacist or doctor to make sure that the benefits of your child taking Telfast outweigh any possible risks.

Keep this leaflet with the medicine.

You may need to read it again.

What Telfast is used for

Telfast contains an active ingredient called fexofenadine hydrochloride. It is one of a group of medicines called antihistamines.

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine, which your body produces when exposed to certain substances.

Telfast is a non-sedating antihistamine which means it has been shown to not cause drowsiness.

Telfast is used to relieve the symptoms of:

- hayfever (seasonal allergic rhinitis) and year round allergies (perennial allergic rhinitis). Symptoms include runny, itchy, blocked nose, sneezing and itchy, watery, red eyes.
- hives or nettle rash (chronic idiopathic urticaria). Symptoms include pink to red, itchy swellings on the skin.

Your pharmacist or doctor may have recommended this medicine for another reason.

Ask your pharmacist or doctor if you have any questions about why this medicine has been recommended for your child.

Before giving it to your child

When it must not be given

Telfast must not be given to your child if your child has had an allergic reaction to fexofenadine, terfenadine (Teldane®) or any of the other ingredients in Telfast. These are listed at the end of this leaflet.

Do not give Telfast to a child under 2 years of age for allergies (allergic rhinitis) or 6 months of age for hives (chronic idiopathic urticaria).

There is currently not enough information available to recommend Telfast for use in children under 2 years of age for allergies and 6 months of age for hives.

Do not give Telfast after the expiry date (EXP) printed on the pack or bottle.

If you give your child this medicine after the expiry date has passed, it may not work as well.

Do not use it if the packaging is damaged or shows signs of tampering.

Before giving it

You should inform your pharmacist or doctor if your child has any allergies to any other medicines, foods, preservatives or dyes.

Your pharmacist or doctor will consider these points when recommending Telfast.

Taking other medicines

Tell your pharmacist or doctor if your child is being given any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines and Telfast may interfere with each other.

Your pharmacist or doctor has more information on medicines to be careful with or to avoid while your child is being given this medicine.

How to give it to your child

How much to give your child

For Hayfever/Allergic Rhinitis:

- **Children 2 - 5 years old:**
5 mL (equivalent to 30 mg) of Telfast Children's Elixir, twice daily, when required.
- **Children 6 - 11 years old:**
5 mL (equivalent to 30 mg) of Telfast Children's Elixir or one 30 mg tablet, twice daily, when required.

For Hives/Nettle Rash:

- **Children 6 - 23 months old:**
2.5 mL (equivalent to 15 mg) of Telfast Children's Elixir twice daily, when required.
- **Children 2 - 5 years old:**
5 mL (equivalent to 30 mg) of Telfast Children's Elixir twice daily, when required.
- **Children 6 - 11 years old:**
5 mL (equivalent to 30 mg) of Telfast Children's Elixir or one 30 mg tablet, twice daily, when required.

For children 12 years of age or older and adults, please refer to Telfast's 60 mg, 120 mg and 180 mg tablets CMI.

Talk to your pharmacist or doctor if you are unsure what dose to give your child.

The dosage directed by your pharmacist or doctor may be different to the recommended dose.

Do not give your child more than the dose your pharmacist or doctor has directed.

How to give it to your child

Measure Telfast Children's Elixir with the spoon included in the package and give to your child.

Give Telfast tablets to your child with a glass of water or as directed by your pharmacist or doctor.

Telfast may be taken with or without food.

How long should it be given for

The duration of treatment depends on the type and duration of your complaint.

Talk to your pharmacist or doctor about how long to give Telfast to your child.

Talk to your pharmacist or doctor if Telfast does not relieve your child's symptoms. Do not give extra elixir or tablets to your child.

If too much is taken (overdose)

If you think that your child or someone else may have taken too much Telfast immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While your child is being given Telfast

Things you must do

Tell all the doctors, dentists and pharmacists who are treating your child that your child is being given Telfast.

If your child is about to be started on any new medicine, tell your pharmacist or doctor that your child is being given Telfast.

If your child is to have surgery that needs a general anaesthetic, tell the doctor or dentist that your child is being given this medicine.

Things you must not do

Do not give your child more than the recommended dose unless your pharmacist or doctor tells you to.

Do not give this medicine to anyone else, even if they have the same symptoms as your child's.

Do not use this medicine to treat any other complaints unless your pharmacist or doctor tells you to.

Side effects

Tell your pharmacist or doctor as soon as possible if your child does not feel well while taking Telfast, even if you do not think the problem is connected with the medicine or is not listed in this leaflet.

All medicines can cause side effects. Sometimes they are serious, most of the time they are not. Your child may need medical treatment if they get some of the side effects. Although most children will not experience any, some of the side effects that may occur with Telfast are:

- headache
- tiredness
- nausea
- dizziness
- drowsiness.

These same effects were seen in patients taking dummy or placebo fexofenadine during the clinical studies.

Ask your pharmacist or doctor to answer any questions you may have.

After giving it to your child

Storage

Keep the tablets in the blister pack until it is time to use them.

If you take the tablets out of the box or blister pack they may not keep well.

Store the bottle or tablets in a cool, dry place at room temperature below 25°C.

Do not store Telfast or any other medicine in the bathroom or near a sink.

Do not leave Telfast in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Telfast where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your pharmacist or doctor tells you to stop giving Telfast to your child, or if the product has passed its expiry date, ask your pharmacist what to do with any left over product.

Product description

What Telfast looks like

Telfast Children's Elixir is a white liquid and is available in a 150 mL bottle.

Telfast 30 mg tablets are round, peach coloured tablets with 03 embossed on one side and 'e' on the other.

They are available in blister packs of 20 tablets.

Ingredients

Active Ingredients

Each 5 mL of elixir contains 30 mg of fexofenadine.

Each tablet contains 30 mg of fexofenadine hydrochloride.

Inactive Ingredients

The elixir also contains:

- butyl hydroxybenzoate

- edetate disodium
- poloxamer 407
- polypropylene glycol
- propyl hydroxybenzoate
- purified water
- raspberry cream flavour
- sodium phosphate dibasic heptahydrate
- sodium phosphate monobasic monohydrate
- sucrose
- titanium dioxide
- xanthan gum
- xylitol

The 30 mg tablets also contain:

- colloidal anhydrous silica
- croscarmellose sodium
- hypromellose
- iron oxide.
- macrogol 400
- magnesium stearate
- microcrystalline cellulose
- povidone
- pregelatinised maize starch
- titanium dioxide

Telfast 30 mg tablets do not contain any gluten, lactose or preservatives.

Sponsor

Telfast is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Australia

Telfast is supplied in New Zealand by:

sanofi-aventis new zealand limited

Level 8, James and Wells Tower

56 Cawley Street

Ellersie, Auckland

New Zealand

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