

Oral Liquid (reformulation) and 6-11 Years Tablets

Active ingredient(s): *Fexofenadine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Telfast. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Telfast.**

Where to find information in this leaflet:

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1. Why is my child using Telfast?

Telfast contains the active ingredient **fexofenadine hydrochloride**. Fexofenadine hydrochloride 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.

2. What should I know before my child uses Telfast?

Warnings

Do not give Telfast to your child if:

- **your child has had an allergic reaction to fexofenadine, terfenadine (Teldane®) or any of the ingredients listed at the end of this leaflet.**

Always check the ingredients to make sure your child can use this medicine.

- **Your child is 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.

- **the expiry date (EXP) printed on the pack or bottle has passed or if the packaging is torn or shows signs of tampering.**

If you give your child this medicine after the expiry date has passed, it may not work as well. If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor or pharmacist 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.
- **takes any medicines for any other condition.**

During treatment, your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

3. What if my child is taking other medicines?

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

Some medicines and Telfast may interfere with each other.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements your child is taking and if these affect Telfast.

4. How do I give Telfast to my child?

How much to give your child

For Hayfever/Allergic Rhinitis:

- **Children 2 - 5 years old:**
5 mL (equivalent to 30 mg) of Telfast Oral Liquid (reformulation), twice daily, when required.
- **Children 6 - 11 years old:**
5 mL (equivalent to 30 mg) of Telfast Oral Liquid (reformulation) or one 6 - 11 Years tablet#, twice daily, when required.

For Hives/Nettle Rash:

- **Children 6 - 23 months old:**
2.5 mL (equivalent to 15 mg) of Telfast Oral Liquid (reformulation) twice daily, when required.
- **Children 2 - 5 years old:**
5 mL (equivalent to 30 mg) of Telfast Oral Liquid (reformulation) twice daily, when required.
- **Children 6 - 11 years old:**
5 mL (equivalent to 30 mg) of Telfast Oral Liquid (reformulation) or one 6 - 11 Years 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.

Follow the instructions provided with the medicine.

Do not exceed the recommended dosage.

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 Telfast to your child

- Measure Telfast Oral Liquid (reformulation) with the measuring device 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 oral liquid or tablets to your child.

If your child takes too much Telfast

If you think that your child has taken too much Telfast, your child may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while my child is taking Telfast?

Things you should do

Remind any doctor, dentist or pharmacist who is 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 should 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.

Looking after your child's medicine

- 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.
- **Keep the medicine in a cool, dry place at room temperature below 30°C for the bottle and store below 30°C for the tablets (manufactured at Sanofi Vietnam). The tablets have two storage conditions available dependent on manufacturer. Refer to product label for instructions regarding storage conditions.**

Follow the instructions in the carton on how to take care of your child's medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your child no longer needs to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not give this medicine to your child after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If your child experiences any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related <ul style="list-style-type: none"> nausea Head and neurology related <ul style="list-style-type: none"> headache tiredness dizziness drowsiness 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects your child experiences, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or Medsafe in New Zealand <https://www.medsafe.govt.nz/safety/report-a-problem.asp#Medicine>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Telfast contains

Active ingredient (main ingredient)	Telfast Oral Liquid (reformulation) - each 5 mL of oral liquid contains 30 mg of fexofenadine. Telfast 6 - 11 Years tablets - each tablet contains 30 mg of fexofenadine hydrochloride.
Other ingredients (inactive ingredients)	Telfast Oral Liquid (reformulation): <ul style="list-style-type: none"> edetate disodium poloxamer 407 propylene glycol purified water raspberry cream flavour sodium phosphate dibasic heptahydrate sodium phosphate monobasic monohydrate sucrose titanium dioxide xanthan gum xylitol potassium sorbate

Telfast 6-11 Years tablets <ul style="list-style-type: none"> colloidal anhydrous silica croscarmellose sodium hypromellose iron oxide macrogol 400 magnesium stearate microcrystalline cellulose povidone pregelatinised maize starch titanium dioxide
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Do not take give this medicine to your child if your child is allergic to any of these ingredients.

Telfast 6 - 11 Years tablet do not contain any gluten, lactose or preservatives.

What Telfast looks like

Telfast Oral Liquid (reformulation) is a white to beige liquid and is available in 60ml and 150 mL bottles (AUST R 418214)

Telfast 6 - 11 Years tablets are round, peach coloured tablets with 03 embossed on one side (AUST R 75139)

They are available in blister packs of 20 and 30 tablets.

#Not marketed

Who distributes Telfast

Telfast is supplied in Australia by:

sanofi-aventis australia pty ltd

87 Yarraman Place, Virginia,

Qld 4014 Australia.

Toll-free: 1800 818 806

Telfast is supplied in New Zealand by:

Healthcare Logistics

58 Richard Pearse Drive Airport Oaks

Auckland New Zealand

Phone: (09) 918 5100

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