

TELFAST[®] ORAL SUSPENSION

Fexofenadine hydrochloride (30mg /5ml)

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What Telfast Oral Suspension is used for

Telfast Oral Suspension is used in children 2 to 11 years of age to relieve the symptoms that occur with hay fever (**seasonal allergic rhinitis**) such as sneezing, itchy, watery or red eyes, itchy or runny nose, itchy throat and nasal congestion.

Telfast Oral Suspension is also used to relieve the symptoms of uncomplicated long term hives, with no known cause (**chronic idiopathic urticaria**) in children 6 months to 11 years of age.

How Telfast Oral Suspension works

Telfast Oral Suspension contains fexofenadine hydrochloride, which is an antihistamine. It works by blocking the action of histamine in order to treat allergy symptoms.

Before you use Telfast Oral Suspension

-When you must not use it

Do not take Telfast Oral Suspension if:

- You are allergic (hypersensitive) to any ingredients of Telfast Oral Suspension

-Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

-Before you start to use it

Avoid the administration together with high-fat foods.

-Taking other medicines

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

- Indigestion remedies (antacids) containing aluminium hydroxide and magnesium may affect the action of Telfast Oral Suspension, by lowering the amount of medicinal products absorbed. It is recommended that you leave about 2 hours between time that you take Telfast and your indigestion remedy.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking this medicine if:

- You are pregnant, might become pregnant, or think you may be pregnant. Telfast Oral Suspension should only be used during pregnancy if necessary.
- You are breast-feeding or planning to breast-feed. Telfast Oral Suspension should only be used during breast-feeding if necessary.

How to use Telfast Oral Suspension

Always take Telfast Oral Suspension exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

- Shake the bottle well before taking Telfast Oral Suspension.
- Only be taken orally
- It is recommended that the dosing syringe included in the carton to be used.

-How much to use

Seasonal Allergic Rhinitis

Children 2 to 11 years

The recommended dose of Telfast Oral Suspension is 30mg (5ml) twice daily.

A dose of 30mg (5ml) once daily is recommended as the starting dose in children with decreased kidney function.

Chronic Idiopathic Urticaria

Children 6 months to less than 2 years

The recommended dose of Telfast Oral Suspension is 15mg (2.5ml) twice daily. For children with decreased kidney function, the recommended

starting dose is 15mg (2.5ml) once daily.

Children 2 to 11 years

The recommended dose of Telfast Oral Suspension is 30mg (5ml) twice daily. For children with decreased kidney function, the recommended starting dose is 30mg (5ml) once daily.

-When to use it

Take Telfast Oral Suspension at about the same time each day, unless your doctor tells you otherwise.

-How long to use it

Keep taking until your doctor tells you to stop. Do not stop taking Telfast just because you feel better. If you stop, your symptoms may return.

-If you forget to use it

- If you forget to take your medicine, leave out that dose completely and take the next dose at the usual time.
- Do not take a double dose to make up for a forgotten tablet.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

-If you use too much (overdose)

Immediately telephone your doctor or go to the nearest hospital emergency department, if you think that you or anyone else may have taken too much Telfast Oral Suspension. Do this even if there are no signs of discomfort or poisoning. Take the medicine pack with you. The following effects may happen: dizziness, drowsiness and dry mouth.

While you are using it

-Things you must do

- Tell all the doctors and pharmacists who are treating you that you are taking Telfast Oral Suspension.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Telfast Oral Suspension.

-Things you must not do

- Do not give this medicine to anyone else, even if they have the same condition as you.

- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Telfast Oral Suspension, or change the dosage, without checking with your doctor.

-Things to be careful of

Driving and using machines

Telfast Oral Suspension is not known to affect your ability to drive and use machines.

Side Effect

Like all medicines, Telfast Oral Suspension can cause side effects, although not everyone gets them.

Do not be alarmed by this list of possible side effects.

You may not experience any of them. Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days.

Common side effects

- Headache
- Drowsiness
- Dizziness
- Nausea

Uncommon side effects

- Fatigue
- Sleeping disorder
- Nervousness
- Alteration in sleep quality or nightmares

Rare side effects

- Urticaria (hives)
- Exanthem (rashes)
- Itching
- Hypersensitive reactions

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Telfast Oral Suspension

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

-Storage

- Keep this medicine in a safe place where children cannot see or reach it.

- Do not use Telfast Oral Suspension after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.
- Store below 30°C. Discard any remaining contents 60 days after first opening the bottle.

-Disposal

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.

Product Description

-What it looks like

White, uniform suspension with raspberry cream aroma. Packages containing one 30ml or 60ml bottle with dosing syringe. Not all pack size is marketed.

-Ingredients:

- Active ingredient:
Each ml contains 6mg of active ingredients, fexofenadine hydrochloride (equivalent to 5.6mg of fexofenadine).
- Inactive ingredients
propylene glycol, disodium EDTA, propylparaben, butylparaben, xanthan gum, poloxamer, titanium dioxide, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, raspberry flavoring cream, sucrose, xylitol and purified water.

-MAL Numbers:

Telfast Oral Suspension
MAL12065070AZ

Manufacturer

Sanofi-Aventis Farmacêutica Ltda.
Rua Conde Domingos Papais, 413
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Product Registration Holder

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