

TELFAS^T DECONGESTANT[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Telfast Decongestant?

Telfast Decongestant contains the active ingredient fexofenadine hydrochloride and pseudoephedrine hydrochloride. Telfast Decongestant is used to relieve the symptoms of seasonal and perennial allergic rhinitis (including hayfever) with sinus/nasal congestion. For more information, see Section [1. Why am I using Telfast Decongestant?](#) in the full CMI.

2. What should I know before I use Telfast Decongestant?

Do not use if you have ever had an allergic reaction to Telfast Decongestant or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Telfast Decongestant?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Telfast Decongestant and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Telfast Decongestant?

- Your pharmacist or doctor will tell you how much Telfast Decongestant you should take.
- The recommended dose for adults and children over the age of 12 years, is one tablet 12 hourly.
- Telfast Decongestant should be swallowed whole with a full glass of water, before a meal.
- Do not take more than the dose your pharmacist or doctor has directed.

More instructions can be found in Section [4. How do I use Telfast Decongestant?](#) in the full CMI.

5. What should I know while using Telfast Decongestant?

Things you should do	<ul style="list-style-type: none">• Tell any doctor, dentist or pharmacist you visit that you are using Telfast Decongestant.• Tell your doctor or pharmacist if you plan to become pregnant, are pregnant, or breastfeeding.
Things you should not do	<ul style="list-style-type: none">• Do not taken more than the recommended dose unless your pharmacist or doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Telfast Decongestant may cause dizziness or light-headedness in some people. If this happens, do not drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep Telfast Decongestant in a cool dry place where the temperature is below 25 degrees C.

For more information, see Section [5. What should I know while using Telfast Decongestant?](#) in the full CMI.

6. Are there any side effects?

Common side effects include headache, dizziness, hallucinations, difficulty sleeping, fatigue, drowsiness, rapid heartbeat, dry mouth, nausea, loss of appetite, nervousness, restlessness, excitability, fear of anxiety and tremor. Serious side effects include symptoms of allergic reaction, including shortness or breath, difficulty breathing, swelling of any part of the face and body, rash, itching or hives on the skin, or urinary retention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TELFAST DECONGESTANT

Active ingredient(s): Fexofenadine hydrochloride/ pseudoephedrine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Telfast Decongestant. **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 Decongestant.**

Where to find information in this leaflet:

- [1. Why am I using Telfast Decongestant?](#)
- [2. What should I know before I use Telfast Decongestant?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Telfast Decongestant?](#)
- [5. What should I know while using Telfast Decongestant?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Telfast Decongestant?

Telfast Decongestant contains two active ingredients - fexofenadine hydrochloride and pseudoephedrine hydrochloride.

Fexofenadine hydrochloride is an antihistamine which is used to help reduce allergic symptoms caused by a substance called histamine. Examples of these include: watery, itchy eyes, sneezing and runny nose.

Pseudoephedrine hydrochloride is a decongestant that works by reducing the amount of fluids in your upper respiratory tract, such as your nose, nasal passages and sinus, which can make it hard to breathe.

Telfast Decongestant is used to relieve the symptoms of seasonal and perennial allergic rhinitis (including hay fever) with sinus/nasal congestion. Symptoms of this can include: nasal and sinus congestion, sneezing, itchy and runny nose, watery eyes and an itchy throat.

2. What should I know before I use Telfast Decongestant?

Warnings

Do not use Telfast Decongestant if you have:

- you are allergic to fexofenadine hydrochloride, pseudoephedrine hydrochloride or terfenadine or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- very high blood pressure
- severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)
- narrow angle glaucoma
- urinary retention
- urinary retention related to urethroprostatic (bladder and prostate) disorders
- a sensitivity to adrenergic events (symptoms include insomnia, dizziness, weakness, tremor or irregular heartbeat)

- taken or stopped taking monoamine oxidase inhibitors (medicines used to treat depression) in the last 14 days.
- history of seizures

Do not give this medicine to a child under the age of 12 years, unless your doctor has told you to.

If you are unsure whether you should start taking this medicine, talk to your pharmacist or doctor.

Check with your doctor if you have any of the following conditions:

- high blood pressure
- hyperthyroidism (overactive thyroid gland)
- diabetes including diabetes mellitus
- heart disease and poor blood flow in the blood vessels of the heart
- glaucoma (high pressure in the eyes)
- prostate problems (including prostatic hypertrophy)
- liver or kidney disease
- hyperreactivity or sensitivity to ephedrine
- psychosis
- onset or worsening of headache

Tell your dentist, pharmacist or doctor if you plan to have surgery. If you have not told your dentist, pharmacist or doctor about any of the above, tell them before you take this medicine.

Your pharmacist or doctor has more information on medicines to be careful with or to avoid while taking this medicine.

During treatment, you 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?](#)

Pregnancy and breastfeeding

Pseudoephedrine is excreted in breast milk.

Do not take this medicine if you are pregnant or plan to become pregnant. If you become pregnant while taking this medicine, stop taking it and tell your pharmacist or doctor immediately.

This medicine is not recommended to be used during pregnancy. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Tell your pharmacist or doctor if you are breastfeeding or planning to breastfeed.

Your pharmacist or doctor will discuss the risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking 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 Decongestant may interfere with each other. These include medicines used to treat:

- depression
- high blood pressure
- heart conditions
- urinary tract infections and bladder problems
- behavioural disorders
- congestion (phenylephrine)
- appetite suppressors
- narrowing blood vessels (medicines administered through the mouth or nose)

These medicines may be affected by Telfast Decongestant, or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your pharmacist or doctor will advise you.

Your pharmacist or doctor has more information on medicines to be careful with or to avoid while taking this medicine.

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

4. How do I use Telfast Decongestant?

How much to take

- Your pharmacist or doctor will tell you how much Telfast Decongestant you should take.
- The recommended dose for adults and children over the age of 12 years, is one tablet 12 hourly.
- Do not take more than the dose your pharmacist or doctor has directed.
- Follow the instructions provided and use Telfast Decongestant until your doctor tells you to stop.
- Talk to your pharmacist or doctor if you are unsure what dose to take.

When to take Telfast Decongestant

- Telfast Decongestant should be taken before a meal.
- You should take the dose at about the same time each day.
- You should avoid taking Telfast Decongestant with or after a high fat meal.

How to take Telfast Decongestant

Telfast Decongestant should be swallowed whole with a full glass of water.

If you forget to take Telfast Decongestant

Telfast Decongestant should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of getting an unwanted side effect.

If you are unsure what to do, ask your pharmacist or doctor. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much Telfast Decongestant

If you think that you have used too much Telfast Decongestant, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)**, 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 using Telfast Decongestant?

Things you should do:

Talk to your pharmacist or doctor if your symptoms don't improve.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Telfast Decongestant. This is important if you are about to be started on any new medicine or if you are having any type of surgery.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking this medicine, stop taking it and tell your pharmacist or doctor immediately.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Pseudoephedrine can lead to positive results in sport doping tests.

Call your doctor straight away if you:

- Do not feel well while you are taking Telfast Decongestant

Things you should not do:

- Do not take 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 condition as you
- Do not take Telfast Decongestant to treat any other complaints unless your pharmacist or doctor tells you to

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Telfast Decongestant affects you.

Telfast Decongestant may cause dizziness or light-headedness in some people.

If this happens, do not drive or operate machinery.

Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

Keep your tablets in the original pack until it is time to take them.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature is below 25 degrees C; for example, do not store it:

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

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Telfast Decongestant.

This medicine helps most people with allergic rhinitis (hayfever) and sinus/nasal congestion, but it may have unwanted side effects in some people.

All medicines can have side effects. If you do experience 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 about side effects.

Children and people over 65 years of age may have an increased chance of getting side effects.

Less serious side effects

Less serious side effects	What to do
<p>General well-being related</p> <ul style="list-style-type: none"> • difficulty sleeping • fatigue • rapid heart beat • dry mouth • nausea • loss of appetite (anorexia) • nervousness • excitability • restlessness • fear of anxiety • tremor <p>Nervous system-related:</p> <ul style="list-style-type: none"> • headache • drowsiness • dizziness • hallucinations 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergy related:</p> <ul style="list-style-type: none"> • shortness of breath • wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • rash, itching or hives on the skin <p>Other:</p> <ul style="list-style-type: none"> • urine retention 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Other side effects (frequency unknown)

Other side effects (frequency unknown)	What to do
<p>Psychiatric related:</p> <ul style="list-style-type: none"> • anxiety • hallucination • inability to sleep • nervousness symptoms such as irritable mood, increased activity or restlessness • low self-esteem • racing thoughts, talking fast and distractibility 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these side effects.</p>
<p>Nervous system related:</p> <ul style="list-style-type: none"> • seizures • stroke • headache • dizziness • shaking known as tremors • sleepiness <p>Heart related:</p> <ul style="list-style-type: none"> • fast or irregular heart beats known as palpitations • high blood pressure • abnormal fast heart beat (fast or irregular) <p>Stomach related:</p> <ul style="list-style-type: none"> • feeling unwell • vomiting • dry mouth • decreased appetite • inflammation of the colon symptoms include diarrhoea, stomach pain <p>Breathing related:</p> <ul style="list-style-type: none"> • shortness of breath <p>Skin and tissue related:</p> <ul style="list-style-type: none"> • rash • hives symptoms include itchy swellings on the skin • itching • excessive sweating 	

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Other side effects (frequency unknown)	What to do
Kidney related: <ul style="list-style-type: none">• difficulty passing urine• pain when passing urine Immune system related: <ul style="list-style-type: none">• allergic reaction Administration site and other: <ul style="list-style-type: none">• tiredness• thirst• unusual weakness• chest pain	

Tell your doctor or pharmacist if you notice anything else that may be making you 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 you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Telfast Decongestant contains

Active ingredient (main ingredient)	Fexofenadine hydrochloride Pseudoephedrine hydrochloride
Other ingredients (inactive ingredients)	microcrystalline cellulose pregelatinised maize starch croscarmellose sodium magnesium stearate carnauba wax stearic acid colloidal anhydrous silica OpadryYS-1-7006 Clear

Do not take this medicine if you are allergic to any of these ingredients.

What Telfast Decongestant looks like

Telfast Decongestant tablets have two layers, are capsule shaped, film coated tablets. One half (lengthwise) of the tablet is off white, and the other half is tan in colour. The off white half of the tablet is marked with "06/012D".

Telfast Decongestant tablets are available in packs of 2, 6 and 10 tablets.

Aust R 72552

Who distributes Telfast Decongestant

sanofi-aventis australia Pty Ltd
12-24 Talavera Road