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:

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

#### 1. Why am I using Telfast?

**Telfast contains the active ingredient fexofenadine hydrochloride.** Telfast 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 not to cause drowsiness.

Telfast is used to relieve the symptoms of hayfever (seasonal allergic rhinitis) in adults and children aged 12 years or older.

Symptoms of hayfever include runny or itchy nose, sneezing, and itchy, watery, red eyes.

Hayfever is usually caused by allergy to various types of pollen from grasses, weeds or trees.

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

#### Warnings

#### Do not use Telfast if:

- you are pregnant, intend to become pregnant, or if you are breastfeeding, unless advised to do so by a Doctor or Pharmacist.
- you are allergic to ingredient fexofenadine hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are under 12 years of age
- the expiry date (EXP) printed on the pack has passed or if the packaging is damaged or shows signs of tampering.

If you take it after the expiry date has passed, it may not work as well.

#### Check with your doctor if you:

- blocked nose without any other symptoms
- symptoms on only one side of your nose
- thick, green or yellow discharge from your nose
- repeated nosebleeds
- loss of smell
- a drip down the back of your throat with thick mucus and/or runny nose
- taste disturbances or loss of taste
- ear pain or discomfort
- pain in your face
- fever

These symptoms are not usually found in hayfever.

If you are taking medicines to treat heartburn and indigestion that contain aluminium or magnesium hydroxide, wait 2 hours before taking Telfast.

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 <u>6. Are there any side effects</u>?

#### Pregnancy and breastfeeding

Do not take Telfast if you are pregnant, intend to become pregnant, or if you are breastfeeding, unless advised to do so by a Doctor or Pharmacist.

## 3. What if I am taking other medicines?

If you are taking medicines to treat heartburn and indigestion that contain aluminium or magnesium hydroxide, wait 2 hours before taking Telfast.

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 may interfere with Telfast and affect how it works.

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.

## 4. How do I use Telfast?

#### How much to take

- For the relief of the symptoms of hayfever, the usual dosage for adults and children over 12 years old is one Telfast 60 mg tablet twice daily or one Telfast 120 mg tablet once daily or as necessary.
- Follow the instructions written on the back of the box.

• If you take the wrong dose, Telfast may not work as well and your hayfever symptoms may not improve.

#### When to take Telfast

- Take Telfast for up to 5 days, if necessary.
- If symptoms persist after 5 days, consult your Doctor or Pharmacist.

#### How to take Telfast

- Take Telfast with a glass of water to make it easier to swallow.
- Telfast may be taken with or without food.

#### If you forget to use Telfast

Do not try to make up for missed doses by taking more than one dose at a time.

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

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to. But if there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

#### If you use too much Telfast

If you think that you have used too much Telfast, you 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 764766), or
- contact your doctor or pharmacist, or
- go to the Emergency Department at your nearest hospital.

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

You may need urgent medical attention.

If you take too much Telfast, you may feel dizzy, drowsy or have a dry mouth.

## 5. What should I know while using Telfast?

#### Things you should do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Telfast.

If you are about to be started on any new medicine, tell your Doctor or Pharmacist that you are taking Telfast.

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

If you become pregnant while taking Telfast, consult your Doctor or Pharmacist.

#### 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 use this medicine to treat any other complaints unless your pharmacist tells you to.

#### Driving or using machines

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

#### Looking after your medicine

- Keep the medicine in a cool, dry place where the temperature stays below 30°C.
- Keep your tablets in the blister pack until it is time to take them.

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

#### 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?

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.

#### Less serious side effects

Less serious side effects	What to do
Gastrointestinal related:	Speak to your doctor if you have any of these less serious side effects and they worry you.
• nausea	
Head and neurology related:	
• headache	
• tiredness	
• dizziness	
• drowsiness	

## 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 (Australia). For NZL reporting can be made online at

https://nzphvc.otago.ac.nz/reporting/ (New Zealand)

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 without a prescription.

## What Telfast contains

Active ingredient (main ingredient)	Telfast 60 mg – 60 mg fexofenadine hydrochloride per tablet
	Telfast 120 mg – 120 mg fexofenadine hydrochloride per tablet
Other ingredients	microcrystalline cellulose
(inactive ingredients)	<ul> <li>pregelatinised maize starch</li> </ul>
	<ul> <li>croscarmellose sodium</li> </ul>
	<ul> <li>magnesium stearate</li> </ul>
	• povidone
	• titanium dioxide
	<ul> <li>colloidal silicon dioxide</li> </ul>
	• macrogol 400
	hypromellose
	<ul> <li>Pigment Blend Pink PB1254</li> </ul>
	• Pigment Blend Yellow PB1255

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

## What Telfast looks like

Telfast 60 mg tablets are peach coloured, oval and double convex in shape, and are available in packs of 10 and 20 tablets. (AUST R 166034)

Telfast 120 mg tablets are peach coloured with a modified capsule shape, and are available in packs of 5 and 10 tablets. (AUST R 166032)

## Who distributes Telfast

Telfast is supplied in Australia by:

Sanofi Consumer Healthcare 87 Yarraman Place Virginia QLD 4014 Australia

Phone: 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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