TELFAST®180mg TABLET

Fexofenadine Hydrochloride (180mg)

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What Telfast 180mg is used for Telfast 180mg are used in adult and adolescents of 12 years and older to relieve the symptoms that occur with

relieve the symptoms that occur with hay fever (seasonal allergic rhinitis) such as sneezing, itchy, watery or red eyes, and itchy or runny nose.

Telfast 180mg is also used to relieve the symptoms of long term hives (chronic idiopathic urticaria - a raised, itchy rash of unknown cause).

How Telfast 180mg works

Telfast 180mg 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 180mg

When you must not use it

Do not take Telfast 180mg if:

• You are allergic (hypersensitive) to fexofenadine or any of the other ingredients of this medicine (listed in Section 8 below).

Before you start to use it

Check with your doctor before taking Telfast 180mg if:

- You have problems with your liver or kidneys
- You are an elderly

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Telfast 180mg.

Pregnancy and breastfeeding Tell your doctor before taking this medicine if you:

• are pregnant or plan to get pregnant.

• are breast-feeding or plan to start breast-feeding.

Fexofenadine hydrochloride should be used during pregnancy and breastfeeding only if the potential benefit justifies the potential risk to the fetus.

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 and magnesium may affect the action of Telfast 180mg, by lowering the amount of medicinal products absorbed. It is recommended to avoid taking your indigestion remedies within 15 minutes before or after taking Telfast 180mg.
- Erythromycin (antibiotic used to treat bacterial infections) or ketoconazole (used to treat fungal infections)

Do not take Telfast 180mg with fruit juices such as grapefruit, orange and apple. It is recommended to take Telfast 180mg with water to maximize the effects of fexofenadine.

How to use Telfast 180mg

Always take Telfast 180mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

• Swallow your tablets orally in whole with plenty of water.

How much to use

Adults and children 12 years of age and older

• The recommended dose is one tablet daily.

Telfast 180mg is not recommended in use for children below 12 years of age.

Kidney impairment

The recommended starting dose in adults with decreased kidney function is 60mg once daily.

When to use it

Take Telfast 180mg 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 180mg just because you feel better. If you stop, your symptoms may return.

If you forget to use it

- If you forget to take your tablet, leave out that dose completely and take the next tablet 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)

If you take too many tablets than you should, tell a doctor or go to a hospital casualty department straight away. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Telfast 180mg.
- Tell your doctor immediately if you become pregnant while taking this medication.

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 180mg, or change the dosage, without checking with your doctor.
- Do not swallow Telfast 180mg with fruit juice.

Things to be careful of

Driving and using machines

Telfast 180mg is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

Side Effect

Like all medicines, Telfast 180mg 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 immediately if you notice any of the following side effects:

- -Menstrual pain
- -Headache
- -Back pain
- -Cough
- -Upper respiratory tract infection
- -Fever
- -Inflammation of the middle ear
- -Vomiting
- -Diarrhoea
- -Tiredness
- -Runny nose
- -Dizziness
- -Stomach discomfort
- -Pain in limbs

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

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 portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Telfast 180mg

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 180mg after the expiry date which is stated on the label

and carton. The expiry date refers to the last day of that month.

• Store below 30°C.

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

Telfast 180mg tablet is a peach, oval, double convex, engraved with '018' on one side and blank on the other side.

Ingredients:

Active ingredient: Each tablet contains 180mg of fexofenadine hydrochloride.

Inactive Ingredients:

Mycrocrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, magnesium stearate, hydroxypropyl methylcellulose (E-15), hydroxypropyl methylcellulose (E-5), povidone, titanium dioxide (E 171), colloidal anhydrous silica, macrogol 400 and pink iron oxide and yellow iron oxide.

MAL number:

Telfast 180mg tablet

MAL20000715A

Manufacturer and Product Registration Holder

<u>Manufacturer</u>

PT Aventis Pharma Jl. Jenderal A. Yani, Pulo Mas, Jakarta, Indonesia.

Product Registration Holder

sanofi-aventis (Malaysia) Sdn. Bhd. Unit TB-18-1, Level 18-1, Tower B, Plaza 33, No.1 Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

Date of revision

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