

TELFAS[®] D TABLET

Fexofenadine Hydrochloride / Pseudoephedrine Hydrochloride (60mg /120mg)

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What Telfast D is used for

Telfast D are used in adult and adolescents of 12 years and older 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.

How Telfast D works

Telfast D contains a combination of two active ingredients, fexofenadine hydrochloride (an antihistamine) and pseudoephedrine hydrochloride (a decongestant). Antihistamine works by blocking the action of histamine in order to reduce allergy symptoms. Decongestant works by reducing congestion in the upper respiratory tract making it easier to breathe.

Before you use Telfast D

When you must not use it

Do not take Telfast D if:

- You are allergic (hypersensitive) to fexofenadine or any of the other ingredients of this medicine (listed in Section 8 below).
- You have increased pressure in the eye (narrow angle glaucoma)
- You have urinary retention problem (inability to empty the bladder).
- You are taking monoamine oxidase inhibitors or within 14 days of stopping such treatment (see taking other medicines)
- You have severe high blood pressure
- You have severe heart problems

- You are sensitive to other adrenergic agents. (Symptoms include insomnia, dizziness, weakness, tremor or irregular heartbeat)

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Telfast D.

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.

Telfast D should be used in pregnancy or breastfeeding only if the potential benefit justifies the potential risk to the fetus or nursing infant.

Before you start to use it

Check with your doctor before taking Telfast D if:

- You have high blood pressure
- You have diabetes
- You have heart disease and poor blood flow in the blood vessels of the heart
- You have overactive thyroid glands (hyperthyroidism)
- You have high pressure in the eyes (glaucoma)
- You have prostate problems
- You have problems with your kidneys
- You are taking other antihistamine or decongestant
- 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 D.

Taking other medicines

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

- Erythromycin (antibiotic used to treat bacterial infections) or ketoconazole (used to treat fungal infections)
- Monoamine oxidase inhibitors (MAOI)-used to treat depression
- Antihypertensive agents (such as methyl dopa, mecamylamine and reserpine)
- Digitalis drugs (such as digoxin) - used to treat various heart conditions.

How to use Telfast D

Always take Telfast-D 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.
- Do not break or chew your tablet.
- Take your tablet before meal.

How much to use

Adults and children 12 years of age and older

- The recommended dose is one tablet twice daily.
- If you have kidney problem, the recommended starting dose is one tablet once daily.

Telfast D is not recommended for children below 12 years of age.

Use in elderly

Use with caution if you are an elderly with decreased liver, kidney or heart function and with other disease or therapy.

When to use it

Take Telfast D 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 D 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.

Symptoms of overdosage include dizziness, drowsiness, dry mouth, headache, nausea, vomiting, sweating, thirst, an abnormally rapid heart rate, irregular heartbeat, difficulty in urination, muscular weakness and tenseness, anxiety, restlessness and insomnia.

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 D.
- 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 D, or change the dosage, without checking with your doctor.

Things to be careful of

Driving and using machines

Telfast D may cause dizziness in some people. If this happens, do not drive or operate machinery.

Side Effect

Like all medicines, Telfast D 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:

- Headache
- Insomnia
- Nausea
- Dry mouth
- Indigestion (dyspepsia)
- Throat irritation
- Dizziness
- Agitation
- Back pain
- Nervousness
- Anxiety
- Abnormal heartbeats
- Upper respiratory infections
- Abdominal pain

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 D

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 D 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 D tablets are bi-layer, capsule shaped, film-coated tablets with one half (lengthwise) white to off-white and the other half tan. The white half of the tablet is debossed with “06/012D”.

Ingredients:

- *Active ingredients* are: Telfast D contains 60mg of fexofenadine hydrochloride and 120mg of pseudoephedrine hydrochloride.
- *Inactive ingredients* are: microcrystalline cellulose, pregelatinized starch, croscarmellose sodium, magnesium stearate, carnauba wax, stearic acid, colloidal silicon dioxide, opadry, purified water.

MAL number:

Telfast D tablet

MAL20040553AR

Manufacturer and Product Registration Holder

Manufacturer

Sanofi Winthrop Industrie
56 route de Choisy au Bac,
60205 Compiègne, France

Product registration holder

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Date of revision

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