

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 hydrochloride or pseudoephedrine hydrochloride or any of the other ingredients of this medicine (listed in Product Description).
- You have increased pressure in the eye (narrow angle glaucoma)
- You have urinary retention problem (inability to empty the bladder).
- You have urinary retention related to urethroprostatic (bladder and prostate) disorders.
- You are taking monoamine oxidase inhibitors or within 14 days of stopping such treatment (see *Taking other medicines*)
- You have severe high blood

pressure or high blood pressure not controlled by medication

- You have severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)
 - You are sensitive to other adrenergic agents. (Symptoms include insomnia, dizziness, weakness, tremor or irregular heartbeat)
 - You have history of seizures
 - You have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure

Do not give this medicine to a child under the age of 12 years.

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.

Pseudoephedrine is excreted in breast milk.

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 (including prostatic hypertrophy)
- You have kidney disease
- You are taking other antihistamine or decongestant
- You are an elderly
- You are hyperreactivity to ephedrine
- You have stroke
- You have mental problem (psychosis)
- You have onset or worsening of headache

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

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.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Inform your doctor or pharmacist if you are taking:

- 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.
- Quinidine (used for irregular heartbeats)
- Tricyclic antidepressant (used for depression)
- Other sympathomimetic amines or vasoconstrictor agents (medicines that stimulate the nervous system or narrow blood vessels)
- Apalutamide (medicine for prostate cancer)
- Antacids

These medicines may be affected by Telfast-D, 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-D.

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. Avoid taking the tablet with fruit juice.
- Do not break or chew your tablet.

- 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.

Take your tablet before meal.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to use it

- Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose, and then go back to taking it as you would normally.
- Do not take a double dose to make up for a missed dose.
- 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.

Taking too much of this medicine may cause symptoms include

dizziness, drowsiness, dry mouth, headache, nausea, vomiting, sweating, thirst, high blood pressure, an abnormally rapid heart rate, sudden irregular heartbeat, chest pain, irritability, convulsions, difficulty in urination, muscular weakness and tenseness, anxiety, restlessness, and insomnia. Some may develop delusions, hallucinations, circulatory collapse, coma, and breathing failure.

While you are using Telfast-D

- 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.
- Talk to your pharmacist or doctor if your symptoms don't improve.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

- 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.
- Do not take more than the dose your pharmacist or doctor has directed.
- Do not take this medicine with fruit juice and antacids

- 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.

Inactive ingredients may occasionally be eliminated in the feces that may look like the original tablet.

Talk to your doctor or pharmacist as one of the active ingredients in Telfast-D, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to

taking more Telfast-D than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section How to use Telfast-D).

Side Effects

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
- Upper respiratory infections
- Abdominal pain
- Sensation of fast or pounding heartbeat (palpitation)
- Hallucination
- Manic symptoms such as High or irritable mood, Inflated self-esteem, Restlessness, Racing thoughts, Talking fast, and Distractibility
- A temporary brain condition that can cause headache, confusion, or vision changes. (Posterior reversible encephalopathy syndrome (PRES))
- A short-term condition where brain blood vessels narrow and cause strong headaches. (Reversible cerebral vasoconstriction syndrome (RCVS))
- Stroke
- Seizures
- Sleepiness
- Tremor
- Irregular heartbeat (arrhythmia)
- Abnormal fast heartbeat (tachycardia)
- High blood pressure
- Vomiting
- Inflammation of the colon symptoms (ischemic colitis)
- Shortness of breath (dyspnea)
- Severe skin reaction: Acute generalized exanthematous pustulosis (AGEP)
- Rash

-Hives symptoms include itchy swellings on the skin (urticaria)

-Itching

-Excessive sweating

-Difficulty passing urine (dysuria)

-Urinary retention

-Thirst

-Tiredness

-Unusual weakness (asthenia)

-Chest pain

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

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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 is a two-layer tablet, one white layer and one tan layer with a clear film coating on the tablet. The tablets are engraved with "06/012D" on the white layer.

- Ingredients:

- Active ingredient(s)

- fexofenadine hydrochloride 60mg
- pseudoephedrine hydrochloride 120mg

- Inactive ingredient(s)

- microcrystalline cellulose
- pregelatinized starch
- croscarmellose sodium
- magnesium stearate
- carnauba wax
- stearic acid
- colloidal silicon dioxide
- opadry YS-1-7006

- MAL number:

MAL20040553ARZ

Manufacturer

Opella Healthcare
International
SAS, Compiègne, France

Product registration holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm, No.
1, Jalan SS7/26A, Kelana Jaya
47301 Petaling Jaya Selangor
Malaysia

Date of revision

20/05/2026

Serial number

BPFK(R4/1)100915/00316