

DETRUSITOL® TABLET

Tolterodine tartrate (2 mg)

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What Detrusitol is used for

Detrusitol is used for the treatment of overactive bladder.

If you have overactive bladder syndrome, you may find that:

- you are unable to control urination;
- you need to rush to the toilet with no advance warning and/or go to the toilet frequently.

How Detrusitol works

Detrusitol belongs to a class of medicines called antimuscarinics. It works by reducing spasm and relaxing the bladder muscles.

Before you use Detrusitol

- When you must not use it

Do not take Detrusitol if you:

- are allergic (hypersensitive) to tolterodine or any of the other ingredients in Detrusitol;
- are unable to pass urine (urinary retention);
- have an uncontrolled narrow-angle glaucoma (uncontrolled high pressure in the eyes with loss of eyesight that is not being adequately treated);
- suffer from myasthenia gravis (excessive weakness of the muscles);
- suffer from severe ulcerative colitis (ulceration and inflammation of the colon);
- suffer from a toxic megacolon (acute expansion of the colon).

Pregnancy and lactation

The safety of Detrusitol during pregnancy has not yet been proven. Detrusitol is not

recommended during pregnancy. You should use Detrusitol only after discussing the potential benefits and the potential risks to your unborn child with your doctor.

It is not known if Detrusitol is excreted in the mother's breast milk. Detrusitol should be avoided during breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Check with your doctor before you use this medicine

- if you have difficulties in passing urine and/or a poor stream of urine;
- if you have a gastro-intestinal disease that blocks the passage of food;
- if you suffer from kidney problems (renal impairment);
- if you have a liver disease;
- if you suffer from neuronal disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system);
- if you have a hiatal hernia (protrusion of upper part of stomach);
- if you ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility);
- if you have a heart condition, such as an abnormal heart tracing (ECG) and slow heart rate (bradycardia);
- if you have abnormally low levels of potassium (hypokalaemia), magnesium (hypomagnesaemia) or calcium (hypocalcaemia) in your blood;
- if you have relevant pre-existing heart diseases, such as:
 - cardiomyopathy (weak heart muscle);
 - myocardial ischaemia (reduced blood flow to the heart);
 - arrhythmia (irregular heartbeat) and heart failure.

Detrusitol contains sodium

Detrusitol 2 mg film-coated tablets contain less than 1 mmol sodium (23 mg) per tablet and therefore is essentially

'sodium free'

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

It is not recommended to use Detrusitol in combination with;

- some antibiotics (e.g. erythromycin, clarithromycin);
- medicines used for the treatment of fungal infections (e.g. ketoconazole, itraconazole);
- antiproteases (medicines used for the treatment of HIV and Hepatitis C);
- medicines that affect the passage of food (e.g. metoclopramide and cisapride);
- medicines for the treatment of irregular heartbeat (e.g. amiodarone, sotalol, quinidine, procainamide);
- other medicines with a similar mode of action to Detrusitol (antimuscarinic properties) or medicines with an opposite mode of action to Detrusitol (cholinergic properties).

How to use Detrusitol

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The usual dose is one 2 mg tablet twice daily, except for people who have a kidney or a liver condition or troublesome side effects in which case your doctor may reduce your dose to one 1 mg tablet twice daily.

Detrusitol is not recommended for children.

- When to use it

Use as directed by your doctor or pharmacist.

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- How long to use it

Continue taking Detrusitol for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do 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. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause accommodation disturbances such as blurred vision and difficulties in passing urine.

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 Detrusitol.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Detrusitol to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. Detrusitol may cause disturbances in accommodation and may change reaction time. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side Effects

Like all medicines, Detrusitol can cause side effects, although not everybody gets them.

Detrusitol may cause mild-to-moderate antimuscarinic effects, like dryness of the mouth, indigestion and dry eyes.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine:

Very common side effects:

- Headache
- Dry mouth

Common side effects:

- Inflammation of lining of airway
- Dizziness
- Sleepiness
- Abnormal skin sensation like tingling, pricking, chilling, burning, or numbness
- Dry eyes
- Abnormal vision including abnormal accommodation
- Vertigo (a feeling of dizziness or "spinning")
- Palpitation (a noticeably rapid, strong, or irregular heartbeat due to agitation, exertion, or illness)
- Indigestion
- Constipation
- Stomach pain
- Excessive amounts of air or gases in the stomach or the intestine
- Vomiting
- Diarrhoea

- Dry skin
- Painful or difficult urination
- Inability to empty the bladder
- Tiredness
- Chest pain
- Accumulation of fluid causing swelling usually in the lower limbs
- Increased weight

There have also been reports of worsening symptoms of dementia (confusion, alteration of mental status, delusion [false belief that is not grounded in reality and persists despite obvious evidence that it is mistaken]) in people being treated for dementia.

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 Detrusitol

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Keep tablets in the original package, protected from moisture.

- 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

Film-coated tablets

The film-coated tablets are white, round and biconvex. The 2 mg tablet is engraved with arcs above and below the letters DT.

DETRUSITOL[®] TABLET

Tolterodine tartrate (2 mg)

- Ingredients

- Active ingredient

Tolterodine tartrate

- Inactive ingredients

Core:

Cellulose, microcrystalline

Calcium hydrogen phosphate

dihydrate

Sodium starch glycolate (Type B)

Magnesium stearate

Colloidal anhydrous silica

Film coating:

Coating granules containing

Hypromellose, cellulose,

microcrystalline, stearic acid,

Titanium dioxide E171

- MAL number

Detrusitol Tablet 2 mg

MAL19991686ACRZ

Manufacturer

Pfizer Italia S.R.L.

Località Marino Del Tronto

63100 Ascoli Piceno, Italy

Product Registration Holder

Viatrix Sdn Bhd

15-03 & 15-04, Level 15, Imazium,

No. 8, Jalan SS 21/37,

Damansara Uptown,

47400 Petaling Jaya,

Selangor, Malaysia.

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02/06/2022

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