

# DETRUSITOL<sup>®</sup> SR EXTENDED RELEASE CAPSULES

Tolterodine L-tartrate (2 mg, 4 mg)

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## What Detrusitol SR is used for

Detrusitol SR is used for the treatment of the symptoms of overactive bladder syndrome.

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 SR works

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

## Before you use Detrusitol SR

### - When you must not use it

Do not take Detrusitol SR if you:

- are allergic (hypersensitive) to Detrusitol SR or any of the other ingredients in Detrusitol SR or to fesoterodine fumarate extended-release tablets;
- are unable to pass urine from the bladder (urinary retention);
- suffer from a condition in which the stomach's ability to empty its contents is impaired (gastric retention);
- have uncontrolled narrow-angle glaucoma (uncontrolled high pressure in the eyes).

## Pregnancy and lactation

The safety of Detrusitol SR during pregnancy has not yet been proven. You should use Detrusitol SR only after discussing the potential benefits and the potential risks to your unborn child with your doctor.

It is not known if Detrusitol SR is excreted in the mother's breast milk. Breast-feeding is not recommended during the usage of Detrusitol SR.

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 ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility);
- if you are being treated for narrow-angle glaucoma (high pressure in the eyes);
- if you suffer from kidney problems (renal insufficiency);
- if you have a liver disease;
- if you suffer from myasthenia gravis (excessive weakness of the muscles);
- if you have a heart condition such as an abnormal heart tracing (ECG).

### - 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.

In particular tell your doctor if you are taking:

- medicines used for the treatment of depression (e.g. fluoxetine);
- medicines used for the treatment of bacterial infections (e.g. clarithromycin);

- medicines used for the treatment of fungal infections (e.g. ketoconazole, itraconazole);
- medicines used for the treatment of HIV (e.g. ritonavir);
- medicines for the treatment of irregular heartbeat (containing, e.g. amiodarone, sotalol, quinidine, procainamide);
- other medicines with a similar mode of action to Detrusitol SR (antimuscarinic properties).

## How to use Detrusitol SR

### - 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 of Detrusitol SR capsules is 4 mg 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 2 mg daily.

If you are taking medicines such as ketoconazole (for fungal infections), clarithromycin (for bacterial infections), ritonavir (for HIV infections), the recommended dose of Detrusitol SR is 2 mg once daily.

Detrusitol SR is not recommended for children and for people with severe liver and kidney problems.

### - When to use it

Use as directed by your doctor or pharmacist.

Detrusitol SR Capsule should be taken with water and swallowed whole.

### - How long to use it

Continue taking Detrusitol SR 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 Detrusitol SR capsules may cause symptoms, such as abnormal heart tracing (ECG) 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 Detrusitol SR.

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

You should see your doctor immediately or go to the casualty department if you experience symptoms of allergic reactions, such as:

- swollen face, tongue or throat
- difficulty to swallow
- hives and difficulty in breathing

- 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 SR 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. 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 SR can cause side effects, although not everybody gets them.

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

Frequent side effects:

dry mouth, headache, constipation and abdominal pain

Side effects reported during post-marketing experience:

- serious allergic reaction which causes difficulty in breathing or dizziness, swelling of the face, lips, mouth, tongue or throat;
- increased heart rate, feeling your heartbeat;
- swelling of the ankles, feet or hands;
- diarrhoea;
- confusion, disorientation (alteration of mental status), memory impairment and hallucinations (seeing, hearing or feeling things that are not really there).

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 calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers→Reporting).

**Storage and Disposal of Detrusitol SR**

- Storage

Do not store above 30°C.

Store in carton to protect from light.

- 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

Detrusitol SR Capsules 2 mg are blue-green with symbol and 2 printed in white ink.

Detrusitol SR Capsules 4 mg are blue with symbol and 4 printed in white ink.

- Ingredients

- Active ingredient  
Tolterodine L-tartrate

-Inactive ingredients

Sugar Spheres, Surelease E-7-19010 Clear, Hydroxypropyl methylcellulose 2910, Blue Opaque Coni-snap Capsule, purified water

- MAL number

Detrusitol SR 2mg Extended Release Capsules  
MAL20021401ACR  
Detrusitol SR 4mg Extended Release Capsules  
MAL20021402ACR

**Manufacturer:**

Catalent Pharma Solutions, LLC  
Winchester, Kentucky 40391, USA

**Product Registration Holder:**

Pfizer (Malaysia) Sdn. Bhd.  
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Wisma Averis, Tower 2  
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