

DETRUSITOL® SR CAPSULES

Tolterodine tartrate (2 mg, 4 mg)

What is in this leaflet

1. What Detrusitol SR is used for
2. How Detrusitol SR works
3. Before you use Detrusitol SR
4. How to use Detrusitol SR
5. While you are using it
6. Side Effects
7. Storage and Disposal of Detrusitol SR
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

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 SR 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. It is not known if Detrusitol SR is excreted in the mother's breast milk. You must discuss with your doctor about the health benefits of breast feeding, underlying maternal condition, and the side effects of Detrusitol SR, on your breastfed baby before taking 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 serious allergic reaction which causes difficulty in breathing or dizziness or low BP;
- if you have skin reaction which causes swelling of the face, lips, mouth, tongue or throat;
- 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 once 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.

DETRUSITOL® SR CAPSULES

Tolterodine tartrate (2 mg, 4 mg)

- 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.

Anticholinergic effects: constipation, blurred vision, somnolence.

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

This medicine contains sucrose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

- 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.

Side effects from clinical study:

- dry mouth
- headache
- tiredness
- dizziness
- constipation
- abdominal pain

- indigestion
- dry eyes
- vision abnormal
- sleepiness
- anxiety
- sinusitis (A condition in which the cavities around the nasal passages become inflamed)
- dysuria (pain, discomfort, or burning when urinating)

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;
- diarrhea;
- 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 visiting the website nppra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Detrusitol SR

- Storage

Please refer to outer carton for storage instructions

DETRUSITOL[®] SR CAPSULES

Tolterodine tartrate (2 mg, 4 mg)

- 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.

Not all strengths are available.

- Ingredients

- Active ingredient
Tolterodine tartrate

- Inactive ingredients
sucrose,
maize starch,
ethylcellulose,
medium chain triglycerides,
oleic acid,
hypromellose,
gelatin.

Both capsule strengths are imprinted with a pharmaceutical grade printing ink that contains
shellac glaze,
titanium dioxide (E171),
indigo carmine (E132),
propylene glycol,
simethicone.

The 2 mg capsules also contain yellow iron oxide (E172).

- MAL number:

Product Name	Registration Number
Detrusitol SR 2 mg Extended Release Capsules	MAL20021401ACRZ
Detrusitol SR 4 mg Extended Release Capsules	MAL20021402ACRZ

Manufacturer

Catalent Pharma Solutions, LLC
Winchester, Kentucky 40391, USA

Product Registration Holder

Viatis Sdn Bhd
15-03 & 15-04, Level 15, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400 Petaling Jaya,
Selangor, Malaysia.

Date of Revision

18/05/2022

Serial Number

NPRA (R1/5) 18052022/136

PLD- DETRUSITOL SR-0522