Package leaflet: Information for the user

Detrusitol SR 2 mg & 4 mg prolonged release capsules, hard
tolterodine tartrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What DETRUSITOL SR is and what it is used for

The active substance in Detrusitol SR is tolterodine. Tolterodine belongs to a class of medicinal products called antimuscarinics.
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.

2. What you need to know before you take DETRUSITOL SR

Do not take Detrusitol SR if you

- are allergic (hypersensitive) to tolterodine or any of the other ingredients in Detrusitol SR (listed in section 6)
- are unable to pass urine from the bladder (urinary retention)
- have an uncontrolled narrow-angle glaucoma (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 dilatation of the colon).

Warnings and precautions
Talk to your doctor or pharmacist before starting your treatment with Detrusitol SR if you think any of these might apply to you.

- If you have difficulties in passing urine and/or a poor stream of urine

- If you have a gastro-intestinal disease that affects the passage and/or digestion of food
- If you suffer from kidney problems (renal insufficiency)
- If you have a liver condition
- 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 (herniation of an abdominal organ)
- 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);
    - a slow heart rate (bradycardia);
    - relevant pre-existing cardiac diseases such as:
        - cardiomyopathy (weak heart muscle)
        - myocardial ischaemia (reduced blood flow to the heart;
        - arrhythmia (irregular heartbeat)
        - and heart failure
- If you have abnormally low levels of potassium (hypokalaemia), calcium (hypocalcaemia) or magnesium (hypomagnesaemia) in your blood

Talk to your doctor or pharmacist before starting your treatment with Detrusitol SR if you think any of these might apply to you.

Other medicines and Detrusitol SR

Tolterodine, the active substance of Detrusitol SR, may interact with other medicinal products.

It is not recommended to use tolterodine in combination with
- some antibiotics (containing e.g. erythromycin, clarithromycin);
- medicinal products used for the treatment of fungal infections (containing e. g. ketoconazole, itraconazole);
- medicinal products used for the treatment of HIV

Detrusitol SR should be used with caution when taken in combination with:
- medicines that affect the passage of food (containing e. g. metoclopramide and cisapride)
- 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) or medicines with an opposite mode of action to Detrusitol SR (cholinergic properties). Ask your doctor if you are unsure.

Detrusitol SR with food and drink
Detrusitol SR can be taken before, after or during a meal.

Pregnancy and breast-feeding

Pregnancy
You should not use Detrusitol SR when you are pregnant. Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to become pregnant.

Breast-feeding
It is not known if tolterodine, the active substance of Detrusitol SR, is excreted in the mother's breast milk. Breast feeding is not recommended during administration of Detrusitol SR.

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

Driving and using machines
Detrusitol SR may make you feel dizzy, tired or affect your sight**;** your ability to drive or operate machinery may be affected.

Detrusitol SR 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 medicinal product.

3. How to take DETRUSITOL SR
Dosage
Always take Detrusitol SR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one 4 mg prolonged-release capsule daily, except for patients who have a kidney or a liver condition or troublesome side effects in which case your doctor may reduce your dose to one 2 mg prolonged-release capsule daily.

Detrusitol SR is not recommended for children.

The prolonged-release capsules are for oral use and should be swallowed whole. Do not chew the capsules.

Duration of treatment
Your doctor will tell you how long your treatment with Detrusitol SR will last. Do not stop treatment early because you do not see an immediate effect. Your bladder will need some time to adapt. Finish the course of prolonged-release capsules prescribed by your doctor. If you have not noticed any effect by then, talk to your doctor.

The benefit of the treatment should be re-evaluated after 2 or 3 months.

Always consult your doctor if you are thinking of stopping the treatment.

If you take more Detrusitol SR than you should:
If you or somebody else takes too many prolonged-release capsules, contact your doctor or pharmacist immediately.

If you forget to take Detrusitol SR
If you forget to take a dose at the usual time, take it as soon as you remember unless it is almost time for your next dose.-In that case, omit the forgotten dose and follow the normal dose schedule.
Do not take a double dose to make up for a forgotten one.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

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

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

You should also seek medical attention if you experience a hypersensitivity reaction (for example itching, rash, hives, difficulty breathing). This occurs uncommonly (occurs in less than 1 in 100 patients).

Tell your doctor immediately or go to the casualty department if you notice any of the following:

- chest pain, difficulty breathing or getting tired easily (even at rest), difficulty breathing at night, swelling of the legs.

These may be symptoms of heart failure. This occurs uncommonly (occurs in less than 1 in 100 patients).

The following side effects have been observed during treatment with Detrusitol SR with the following frequencies.

Very common**:** may affect more than 1 in 10 people

- Dry mouth

Common: may affect up to 1 in 10 people

- Sinusitis
- Dizziness, sleepiness, headache
- Dry eyes, blurred vision
- Difficulty in digestion (dyspepsia), constipation, abdominal pain, excessive amounts of air or gases in the stomach or the intestine
- Painful or difficult urination
- Tiredness
- Extra fluid in the body causing swelling (e.g. in the ankles)
- Diarrhoea

Uncommon: may affect up to 1 in 100 people

- Allergic reactions
- Nervousness
- Sensation of pins and needles in the fingers and toes
- Vertigo
- Palpitations, heart failure, irregular heartbeat
- Inability to empty the bladder
- Chest pain
- Memory impairment

Additional reactions include severe allergic reactions, confusion, hallucinations, increased heart rate, flushed skin, heart burn, vomiting, angioedema, dry skin and disorientation. There have also been reports of worsening symptoms of dementia in patients being treated for dementia.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DETRUSITOL SR

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label/carton. The expiry date refers to the last day of that month.

Do not store above 25ºC.

Bottle: Store in the original container.

Blisters: Keep the blister in the outer carton.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Detrusitol SR contains
The active substance in Detrusitol SR 2 mg prolonged-release capsules is tolterodine.
Each capsule contains 2 mg of tolterodine tartrate, equivalent to 1.37 mg of tolterodine.

The active substance in Detrusitol SR 4 mg prolonged-release capsules is tolterodine.
Each capsule contains 4 mg of tolterodine tartrate, equivalent to 2.74 mg of tolterodine.

The other ingredients are:
Capsule contents: Sugar spheres (containing sucrose and maize starch) [See section 2 Detrusitol SR contains sucrose (a type of sugar)], hypromellose and Surelease E-7-19040 (containing ethylcellulose, medium chain triglycerides and oleic acid).

Capsule shell: Gelatin and colourants

Colourants:
Blue-green 2 mg prolonged release capsule: Indigo carmine (E132), titanium dioxide (E171) and yellow iron oxide (E172).
Blue 4 mg prolonged release capsule: Indigo carmine (E132) and titanium dioxide (E171).

Printing ink: Shellac glaze (E904), titanium dioxide (E171), propylene glycol (E1520) and simeticone.

What Detrusitol SR looks like and contents of the pack

Detrusitol SR is a hard prolonged release capsule designed for once daily dosing.

Detrusitol SR 2 mg prolonged release capsules are blue-green and marked with white printing (symbol and 2).

Detrusitol SR 4 mg prolonged release capsules are blue and marked with white printing (symbol and 4).

Detrusitol SR 2 mg and 4 mg prolonged release capsules are available in the following pack sizes:

Blister packs containing;

- 7 prolonged-release capsules
- 14 prolonged-release capsules
- 28 prolonged-release capsules
- 49 prolonged-release capsules
- 84 prolonged-release capsules
- 98 prolonged-release capsules
- 280 prolonged-release capsules

And bottles containing 30, 100 and 200 capsules.
Hospital packs are available in packs of 80, 160 and 320 capsules.
Please note that not all the above pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Upjohn EESV
Rivium Westlaan 142
2909 LD Capelle aan den IJssel
Netherlands

Manufacturer:
Pfizer Italia S.r.l
Località Marino del Tronto
63100 Ascoli Piceno (AP)
Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Detrusitol retard: Austria, Belgium, Luxembourg, Denmark, Germany Iceland, Italy and Portugal
Detrusitol SR: Finland Greece, Ireland, Netherlands, Norway, Sweden
Detrusitol L.P. France,
Detrusitol Neo: Spain
Detrusitol XL UK

This leaflet was last approved on 12/2024.