PATIENT INFORMATION LEAFLET

Detrusitol® SR 2 mg & 4mg Prolonged-release Capsules

Tolterodine tartrate

Read all of this leaflet carefully before you start using this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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. 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
- 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).

Take special care with DETRUSITOL SR
- 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.

Taking other medicines
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.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking 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.

Important information about some of the ingredients of Detrusitol SR
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. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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 have taken 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Detrusitol SR 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 side effects (occurs in more than 1 in 10 patients) are:
- Dry mouth

Common side effects (occurs in less than 1 in 10 patients) are:
- 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 side effects (occurs in less than 1 in 100 patients) are:
- 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DETRUSITOL SR

Keep Detrusitol SR out of the reach and sight of children.
Do not use Detrusitol SR 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 30°C.
Do not store above 25°C (Santizor XL – UK)
Keep the blister in the outer carton.
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.

6. FURTHER INFORMATION

What Detrusitol SR contains
The active substance in Detrusitol SR 2 mg prolonged release capsules is 2 mg of tolterodine tartrate, equivalent to 1.37 mg of tolterodine.
The active substance in Detrusitol SR 4 mg prolonged release capsules is 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), hypromellose and Surelease E-7-19010 (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, titanium dioxide (E171), propylene glycol and simeticone.

Product procured from within the EU & repackaged by the parallel product authorisation holder
PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

Parallel Product Authorisation Number:
Detrusitol SR 2 mg Prolonged-release Tablets: 465/80/4
Detrusitol SR 4 mg Prolonged-release Tablets: 465/80/3

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

Detrusitol is a registered trademark of Pfizer Health AB.

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

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