

PACKAGE LEAFLET: INFORMATION FOR THE USER

Detrusitol XL 4 mg prolonged-release capsules, hard Tolterodine

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 XL is and what it is used for
2. Before you take Detrusitol XL
3. How to take Detrusitol XL
4. Possible side effects
5. How to store Detrusitol XL
6. Further information

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

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

Detrusitol XL 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 XL

Do not take Detrusitol XL if you:

- are allergic (hypersensitive) to tolterodine or any of the other ingredients in Detrusitol XL
- 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 XL

- 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 XL if you think any of these might apply to you.

Taking other medicines

Tolterodine, the active substance of Detrusitol XL, 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 XL 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 XL (antimuscarinic properties) or medicines with an opposite mode of action to Detrusitol XL (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 XL with food and drink

Detrusitol XL can be taken before, after or during a meal.

Pregnancy and breast-feeding**Pregnancy**

You should not use Detrusitol XL 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 XL, is excreted in the mother's breast milk. Breast-feeding is not recommended during administration of Detrusitol XL.

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

Driving and using machines

Detrusitol XL 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 XL

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 XL**Dosage**

Always take Detrusitol XL 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 2 mg Detrusitol daily.

Detrusitol XL 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 XL 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 XL 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 XL

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 XL 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 XL 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 with 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 reported 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DETRUSITOL XL

Keep Detrusitol XL out of the reach and sight of children.

Do not use Detrusitol XL 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.

Bottle: Store in the original container.

Blisters: 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 XL contains

The active substance in Detrusitol XL 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: Gelatine and colourants.

Colourants:

Blue 4 mg prolonged-release capsule: Indigo carmine (E132) and titanium dioxide (E171).

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

What Detrusitol XL looks like and contents of the pack

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

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

Detrusitol XL 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:

Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
UK

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 and Sweden

Detrusitol L.P. France

Detrusitol Neo: Spain

Detrusitol XL: UK

This leaflet was last revised: 07/2015

DT 15_0 UK