

PACKAGE LEAFLET: INFORMATION FOR THE USER

Detrusitol® 1mg film-coated tablets (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.

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2. Before you take Detrusitol
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1. What Detrusitol is and what it is used for

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

Detrusitol 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

Do not take Detrusitol if you:

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

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

Taking other medicines

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

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

Pregnancy and breast-feeding

Pregnancy

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

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

Driving and using machines

Detrusitol may make you feel dizzy, tired or affect your sight; your ability to drive or operate machinery may be affected.

3. How to take Detrusitol

Dosage

Always take Detrusitol 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 2mg tablet twice 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 1mg tablet twice daily.

Detrusitol is not recommended for children.

The tablets are for oral use and should be swallowed whole.

Duration of treatment

Your doctor will tell you how long your treatment with Detrusitol 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 tablets 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 than you should

If you or somebody else takes too many tablets, contact your doctor or pharmacist immediately.

If you forget to take Detrusitol

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 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 with the following frequencies.

Very common side effects (occurs in more than 1 in 10 patients) are:

- Dry mouth
- Headache

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

- Bronchitis
- Dizziness, sleepiness, sensation of pins and needles in the fingers and toes
- Dry eyes, blurred vision
- Vertigo
- Palpitations
- Difficulty in digestion (dyspepsia), constipation, abdominal pain, excessive amounts of air or gases in the stomach or the intestine, vomiting
- Dry skin
- Painful or difficult urination, inability to empty the bladder

- Tiredness, chest pain, extra fluid in the body causing swelling (e.g. in the ankles)
- Increased weight
- Diarrhoea

Uncommon side effects (occurs in less than 1 in 100 patients) are:

- Allergic reactions
- Nervousness
- Increased heart rate, heart failure, irregular heartbeat
- Heart burn
- Memory impairment

Additional reactions reported include severe allergic reactions, confusion, hallucinations, flushed skin, angioedema, 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie e-mail: medsafety@hpra.ie

5. How to store Detrusitol

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

Do not use this medicine after the expiry date (Exp) which is stated on the carton and blister. The expiry date refers to the last day of that month.

No special precautions for storage.

If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.

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.

If you have any left-over/unused tablets, please return these to your pharmacist for safe disposal.

6. Further information

What Detrusitol contains

The active substance in Detrusitol 1mg tablets is 1mg of tolterodine tartrate, equivalent to 0.68mg of tolterodine.

The other ingredients are:

Core

Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium carboxymethyl starch (Type B), magnesium stearate and colloidal silicon dioxide.

Film coating

Hypromellose, microcrystalline cellulose, stearic acid and titanium dioxide (E171).

What Detrusitol looks like and contents of the pack

Detrusitol 1mg tablets are white, round, biconvex and marked with arcs above and below the lettering TO.

Detrusitol 1mg is available in a blister pack containing 56 tablets.

Manufacturer

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

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

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This medicinal product is authorised in the following Member States of the EEA under the trade name **Detrusitol**: Austria, Belgium, Luxembourg, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, United Kingdom.

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Is this leaflet hard to see or
read?
Call +44 (0) 1302 365000
(Regulatory)**