Package leaflet: Information for the user
Detrusitol 1 mg & 2 mg film-coated tablets
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 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. What you need to know before you take DETRUSITOL

Do not take Detrusitol if you

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

Other medicines and Detrusitol
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.

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.

Detrusitol contains sodium
Detrusitol contains less than 1 mmol sodium (23 mg) per 1 mg and 2 mg film-coated tablets, that is to say essentially 'sodium-free'.

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 2 mg 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 1 mg 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 take 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 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 with the following frequencies.

Very common: may affect more than 1 in 10 people

- Dry mouth
- Headache

Common: may affect up to 1 in 10 people

- 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: may affect up to 1 in 100 people

- 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.

Ireland
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 which is stated on the label/carton. The expiry date refers to the last day of that month.

No special precautions for storage.

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 protect the environment.

6. Contents of the pack and other information

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

The active substance in Detrusitol 2 mg tablets is tolterodine.
Each tablet contains 2 mg of tolterodine tartrate, equivalent to 1.37 mg of tolterodine.

The other ingredients are:
Core: Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium starch glycollate (Type B) (See section 2 “Detrusitol contains sodium”), magnesium stearate and colloidal anhydrous silica.

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

What Detrusitol looks like and contents of the pack

Detrusitol 1 mg tablets are white, round, biconvex and marked with arcs above and below the lettering TO.
Detrusitol 2 mg tablets are white, round, biconvex and marked with arcs above and below the lettering DT.

Detrusitol 1 mg and 2 mg tablets are available in the following pack sizes:
Blister packs containing;

- 20 tablets (2 strips of 10)
- 30 tablets (3 strips of 10)
- 50 tablets (5 strips of 10)
- 100 tablets (10 strips of 10)
- 14 tablets (1 strip of 14)
- 28 tablets (2 strips of 14)
- 56 tablets (4 strips of 14)
- 280 tablets
- 560 tablets

Bottles containing 60 or 500 tablets.
Please note that not all the above pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Ireland
Viatris Healthcare Limited,
Damastown Industrial Park,
Mulhuddart,
Dublin 15
DUBLIN,
Ireland

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

Italy

Or

allphamed PHARBIL Arzneimittel GmbH
Hildebrandstr. 10-12
37081 Göttingen
Germany

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

This leaflet was last revised 02/2026