

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tolusitol 2 mg Hard Prolonged-Release Capsules
Tolusitol 4 mg Hard Prolonged-Release Capsules

Tolterodine tartrate



Read all of this leaflet carefully before you start taking 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.

In this leaflet:

1. What Tolusitol is and what it is used for
2. What you need to know before you take Tolusitol
3. How to take Tolusitol
4. Possible side effects
5. How to store Tolusitol
6. Contents of the pack and other information.

1. What Tolusitol is and what it is used for

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

Tolusitol 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 Tolusitol

Do not take Tolusitol if you:

- are allergic to tolterodine or any of the other ingredients of this medicine (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 taking Tolusitol

- 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 neurological disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system).
- If you have a hiatus 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 Tolusitol if you think any of these might apply to you.

Other medicines and Tolusitol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

It is not recommended to use Tolusitol 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

Tolusitol 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 Tolusitol (antimuscarinic properties) or medicines with an opposite mode of action to Tolusitol (cholinergic properties). The reduction in gastric motility caused by antimuscarinics may affect the absorption of other drugs. Ask your doctor if you are unsure.

Tolusitol with food and drink

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

Pregnancy, breast-feeding and fertility

Pregnancy

You should not use Tolusitol 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 Tolusitol, is excreted in the mother's breast milk.

Breast-feeding is not recommended during administration of Tolusitol.

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

Driving and using machines

Tolusitol may make you feel dizzy, tired or affect your sight. If you experience any of these affects then you should not drive your car or operate heavy machinery.

Tolustiol contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctore before taking this medicinal product.

3. How to take Tolusitol

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The prolonged-release hard capsules are for oral use and should be swallowed whole.

Do not chew the capsules.

Adults:

The usual dose is one 4 mg prolonged-release hard capsule daily.

Patients with liver or kidney problems:

In patients with liver or kidney problems your doctor may reduce your dose to 2 mg Tolusitol daily.

Children:

Tolusitol is not recommended for children.

If you take more Tolusitol than you should:

If you or somebody else takes too many prolonged-release capsules, contact your doctor or pharmacist immediately. Symptoms in case of overdose include hallucinations, excitation, a heartbeat faster than usual, dilation of the pupil and inability to urinate or breathe normally.

If you forget to take Tolusitol:

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 stop taking Tolusitol

Your doctor will tell you how long your treatment with Tolusitol 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.

continued on the next page >>

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 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 (may affect up to 1 in 100 people).

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 (may affect up to 1 in 100 people).

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

Very common side effects (may affect more than 1 in 10 people) are:

- Dry mouth

Common side effects (may affect up to 1 in 10 people) are:

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| • 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 | • Diarrhoea |
| • Extra fluid in the body causing swelling (e.g. in the ankles) | • Tiredness |

Uncommon side effects (may affect up to 1 in 100 people) are:

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| • Allergic reactions | • Heart failure |
| • Nervousness | • Irregular heartbeat |
| • Palpitations | • Chest pain |
| • Inability to empty the bladder | • Sensation of pins and needles in the fingers and toes |
| • Vertigo | • 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: + 353 1 6764971; Fax: + 353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tolusitol

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 25 °C

HDPE bottle: Shelf life after first opening is 200 days

Do not throw away medicines 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 Tolusitol contains

The active substance in Tolusitol 2 mg Hard Prolonged-Release Capsules is 2 mg of tolterodine tartrate, equivalent to 1.37 mg of tolterodine.

The active substance in Tolusitol 4 mg Hard Prolonged-Release Capsules is 4 mg of tolterodine tartrate, equivalent to 2.74 mg of tolterodine.

The other ingredients are:

Lactose monohydrate, cellulose microcrystalline, poly(vinyl acetate), povidone, silica, sodium laurilsulfate, sodium docusate, magnesium stearate, hydroxypropylmethylcellulose
Capsule composition: indigo carmine (E132), quinoline yellow (only in 2 mg) (E104), titanium dioxide (E171), gelatin
Inner tablet coating: ethylcellulose, triethyl citrate, methacrylic acid - ethyl acrylate copolymer, 1,2-Propylene glycol.

What Tolusitol looks like and contents of the pack

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

Tolusitol 2 mg Hard Prolonged-Release Capsules are opaque green-opaque-green containing two white, round, biconvex coated tablets.

Tolusitol 4 mg Hard Prolonged-Release Capsules are light blue-opaque-light blue opaque containing four white, round, biconvex coated tablets

Tolusitol 2 mg Hard Prolonged-Release Capsules are available in the following pack sizes:

Blister packs containing: 7, 14, 28, 30, 49, 50, 56, 80, 84, 90, 98, 100, 112, 160, 280, 320 prolonged-release hard capsules

Tolusitol 4 mg Hard Prolonged-Release Capsules are available in the following pack sizes:

Blister packs containing: 7, 14, 28, 30, 49, 50, 56, 80, 84, 90, 98, 100, 112, 160, 280, 320 prolonged-release hard capsules

HPDE bottles containing: 30, 60, 100 and 200 hard prolonged-release capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co. Cork. Ireland.

Manufacturers:

Pharmathen S.A., 6. Dervenakion Str., 153 51 Pallini Attiki, Greece.
Pharmathen International S.A. Sapes Industrial Park, Block 5, 69300 Rodopi, Greece.
Portfarma ehf, Borgartúni 26, 105 Reykjavík, Iceland.
Pharmadox Healthcare Ltd., KW20A Kordin Industrial Park, Paola, PLA 3000, Malta.
Pharmacare Premium Ltd., HHF 003, Hal Far Industrial Estate, Birzebbugia BBG3000, Malta.
Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

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

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| UK: | Inconex XL 2mg, 4mg prolonged release capsules, hard |
| BE: | Tolterodin Sandoz 2mg, 4mg, harde capsules met verlengde afgifte |
| BG: | Tolterodine Sandoz |
| DE: | Tolterodin 1 A Pharma 2mg/ 4mg Hartkapseln retardiert |
| DK: | Tolterodine Sandoz |
| ES: | Tolterodina Neo Sandoz 2mg/4 mg cápsulas de liberación prolongada EFG |
| EL: | Tolterodine Sandoz |
| FI: | Tolterodine Sandoz |
| IE: | Tolusitol 2 mg/4 mg Hard Prolonged-Release Capsules |
| IS: | Tolterodine Sandoz |
| LU: | Tolterodin Sandoz 2mg/ 4mg, gelules a liberation prolongee |
| MT: | Iconex XL 2mg/4mg prolonged release capsules, hard |
| NL: | Tolterodinetartraat Sandoz retard 2mg/4 mg, harde capsules met verlengde afgifte |
| NO: | Tolterodine Sandoz |
| SE: | Tolterodine Sandoz |

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