Package leaflet: Information for the patient

Tolusitol 2 mg prolonged-release hard capsules
Tolusitol 4 mg prolonged-release hard 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.

What is in this leaflet

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 gastrointestinal 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 and breast-feeding
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 effects, then you should not drive your car or operate heavy machinery.

Tolusitol contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol (23 mg) sodium per prolonged-release hard capsule, that is to say essentially 'sodium-free'.

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.

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:

- Sinusitis
- Sleepiness
- Dry eyes
- Difficulty with digestion (dyspepsia)
- Abdominal pain
- Painful or difficult urination
- Extra fluid in the body causing swelling (e.g. in the ankles)
- Dizziness
- Headache
- Blurred vision
- Constipation
- Excessive amounts of air or gases in the stomach or the intestine
- Diarrhoea
- Tiredness.

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

- Allergic reactions
- Nervousness
- Palpitations
- Inability to empty the bladder
- Vertigo
- Heart failure
- Irregular heartbeat
- Chest pain
- Sensation of pins and needles in the fingers and toes
- 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 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 and carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C

Shelf life after first opening:
HDPE bottle: 200 days

Do not throw away any 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 is tolterodine tartrate.
  Each prolonged-release hard capsule contains 2 mg of tolterodine tartrate.
  Each prolonged-release hard capsule contains 4 mg of tolterodine tartrate.

2 mg prolonged-release hard capsules:
- The other ingredients are lactose monohydrate, microcrystalline cellulose, poly(vinyl acetate), povidone, colloidal anhydrous silica, sodium laurilsulfate, sodium docusate, magnesium stearate, hydroxypropyl methylcellulose, indigo carmine (E132), quinoline yellow (E104), titanium dioxide (E171), gelatine, ethylcellulose, triethyl citrate, methacrylic acid - ethyl acrylate copolymer, 1,2-Propylene glycol.

4 mg prolonged-release hard capsules:
- The other ingredients are lactose monohydrate, microcrystalline cellulose, poly(vinyl acetate), povidone, colloidal anhydrous silica, sodium laurilsulfate, sodium docusate, magnesium stearate, hydroxypropyl methylcellulose, indigo carmine (E132), titanium dioxide (E171), gelatine, ethylcellulose, triethyl citrate, methacrylic acid - ethyl acrylate copolymer, 1,2-Propylene glycol.

What Tolusitol looks like and contents of the pack
2 mg prolonged-release hard capsules:
Opaque green-opaque green hard gelatine capsules containing two white, round, biconvex tablets.

4 mg prolonged-release hard capsules:
Light blue opaque-light blue opaque hard gelatine capsules containing four white, round, biconvex tablets.

The prolonged release hard capsules are packed in Alu/PVC/PE/PVDC blister, or are packed in a HDPE bottle with a tamper-evident closure and inserted in a carton.

Pack sizes:
Blister: 7, 14, 28, 30, 49, 50, 56, 80, 84, 90, 98, 100, 112, 160, 280, 320 prolonged-release hard capsules
Bottle: 30, 60, 100 and 200 prolonged-release hard 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.
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:

Belgium	Tolterodin Sandoz 4mg capsules met verlengde afgifte, hard
Denmark	Tolterodine "Sandoz"
Finland	Tolterodine Sandoz 4 mg, depotkapselit, kovat
Germany	Tolterodin - 1 A Pharma 4 mg Hartkapseln, retardiert
Greece	Tolterodine/Sandoz 2 mg καψάκια παρατεταμένης αποδέσμευσης, σκληρά
Iceland	Tolterodine Sandoz 4 mg, forðahylki, hörð
Ireland	Tolusitol 2mg prolonged-release hard capsules
	Tolusitol 4mg prolonged-release hard capsules
Malta	Inconex XL 2mg, prolonged release capsules, hard
	Inconex XL 4mg, prolonged release capsules, hard
Netherlands	Tolterodinetartraat Sandoz retard 2mg, capsules met verlengde afgifte, hard
	Tolterodinetartraat Sandoz retard 4mg, capsules met verlengde afgifte, hard
Norway	Tolterodine Sandoz 2 mg depotkapsler, harde
	Tolterodine Sandoz 4 mg depotkapsler, harde
Spain	Tolterodina Neo Sandoz 4 mg cápsulas de liberación prolongada EFG
Sweden	Tolterodine Sandoz 2 mg, depotkapslar, hårda
	Tolterodine Sandoz 4 mg, depotkapslar, hårda
United Kingdom	Inconex XL 2 mg Prolonged-release Capsules, hard
	Inconex XL 4 mg, Prolonged-release Capsules, hard

This leaflet was last revised in 09/2019.