Package leaflet: Information for the user

Toltertan SR 2mg Prolonged-release Capsules, Hard
Toltertan SR 4mg Prolonged-release Capsules, Hard

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. 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, pharmacist or nurse. See section 4.

What is in this leaflet:

1. What Toltertan SR is and what it is used for

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

Toltertan SR 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 Toltertan SR

Do not take Toltertan SR if you
- are allergic (hypersensitive) to tolterodine or any of the other ingredients in
- Toltertan SR (see section 6 for a list of the ingredients).
- are unable to pass urine from the bladder (urinary retention).
- have an uncontrolled narrow-angle glaucoma (high pressure in the eyes with loss of eye sight 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 atoxic megacolon (acute dilatation of the colon).

Warnings and precautions

Talk to your doctor before taking Toltertan SR if you:
- have difficulties in passing urine and /or a poor stream of urine.
- have a gastro-intestinal disease that affects the passage and /or digestion of food.
- suffer from kidney problems (renal insufficiency).
- have a liver condition.
- suffer from neurological disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system).
- have a hiatus hernia (herniation of an abdominal organ).

- ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility).
- have a heart condition such as:
  - an abnormal heart tracing (ECG)
  - a low heart rate (bradycardia)
  - relevant pre-existing cardiac diseases such as: cardiomyopathy (weak heart muscle), myocardial ischaemia (reduced blood flow to the heart), arrhythmia (irregular heart beat) and heart failure
- have abnormally low levels of potassium (hypokalaemia), calcium (hypocalcaemia) or magnesium (hypomagnesaemia) in your blood.

Other medicines and Toltertan SR
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tolterodine, the active substance of Toltertan SR, 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

Toltertan SR 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 heart beat (containing e.g. amiodarone, sotalol, quinidine, procainamide)
- other medicines with a similar mode of action to Toltertan SR (antimuscarinic properties) or medicines with an opposite mode of action to Toltertan SR (cholinergic properties). The reduction in gastric motility caused by antimuscarinics may affect the absorption of other drugs. Ask your doctor if you are unsure.

Toltertan SR with food and drink
Toltertan SR can be taken before, after or during a meal.

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

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

Driving and using machines
Toltertan SR 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.

Toltertan SR 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 medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially

'sodium-free'.

3. How to take Toltertan SR

Dosage:
Always take Toltertan SR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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 Toltertan SR daily.

Use in children
Toltertan SR is not recommended for children.

Method of administration
The prolonged-release hard 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 Toltertan SR 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 take more Toltertan SR 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 Toltertan SR
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, Toltertan SR 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 Toltertan SR with the following frequencies.

Very common (may affect more than 1 in 10 people):
- dry mouth

Common (may affect up to 1 in 10 people):
- 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 (may affect up to 1 in 100 people):
- allergic reactions
- nervousness
- palpitations
- inability to empty the bladder
- vertigo
- heart failure
- irregular heart beat
- 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, heartburn, 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 the national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Toltertan SR

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 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 Toltertan SR contains

The active substance in Toltertan SR 2 mg prolonged-release capsules, hard is 2 mg of tolterodine tartrate, equivalent to 1.37 mg of tolterodine.
The active substance in Toltertan SR 4 mg prolonged-release capsules, hard 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, hydroxypropylmethyl cellulose.

Capsule composition: indigo carmine (E132), titanium dioxide (E171), gelatin, quinolone yellow (E104).

Inner tablet coating:
Ethylcellulose, triethyl citrate, methacrylic acid - ethyl acrylate copolymer, 1,2-propylene glycol.

What Toltertan SR looks like and contents of the pack

Toltertan SR is a hard prolonged-release capsule designed for once daily dosing.
Toltertan SR 2 mg prolonged-release hard capsules are opaque green.
Toltertan SR 4 mg prolonged-release hard capsules are light blue opaque.

Toltertan SR 2 mg prolonged-release hard capsules are available in the following pack sizes:
Blister packs containing: 28, 30, 100 prolonged-release capsules.
HDPE bottles containing 30, 100 capsules.

Toltertan SR 4 mg prolonged-release hard capsules are available in the following pack sizes:
Blister packs containing: 7, 14, 28, 30, 49, 56, 84, 98, 100, 112, 126 prolonged-release capsules.
HDPE bottles containing: 30, 100 capsules.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder:
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:
Pharmathen S.A , 6 Dervenakion Str., 153 51 Pallini Attiki, Greece
Pharmathen, International S.A, Sapes Industrial Park, Block 5, 69300 Rodopi, Greece
LAMP SAN PROSPERO S.p.A., Via della Pace, 25/A, 41030 San Prospero, Modena, Italy
STADA Arzneimittel AG, Stadastrasse 2 – 18, 61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

United Kingdom:	Toltrat XL 2 mg and 4 mg prolonged-release capsules
Denmark:	Tolterodin STADA
Ireland:	Toltertan SR 2 mg and 4 mg prolonged-release capsules
Spain:	Tolterodina Neo STADA 4 mg cápsules duras de liberción prolongada EFG
Sweden:	Tolterodin STADA depotkapslar, hårda

This leaflet was last revised in May 2020.