Package leaflet: Information for the user

Tolthen XL 2 mg prolonged-release capsules, hard
Tolthen XL 4 mg prolonged-release capsules, hard

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 Tolthen XL is and what it is used for

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

Tolthen XL 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 Tolthen XL

Do not take Tolthen XL 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

Take special care with Tolthen XL

- 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 taking Tolthen XL if you think any of these might apply to you.

Other medicines and Tolthen XL

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

Tolterodine, the active substance of Tolthen XL 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.

Tolthen XL 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 Tolthen XL (antimuscarinic properties) or medicines with an opposite mode of action to Tolthen XL (cholinergic properties). Ask your doctor if you are unsure.

Tolthen XL with food and drink

Tolthen XL can be taken before, after or during a meal.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You should not use Tolthen XL when you are pregnant.

Breast-feeding

It is not known if tolterodine, the active substance of Tolthen XL, is excreted in the mother's breast milk. Breast-feeding is not recommended during administration of Tolthen XL.

Driving and using machines

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

Tolthen XL contains lactose

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

Tolthen XL contains sodium

This medicine contains 0.00404 mmol (or 0.092988 mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

3. How to take Tolthen XL

Dose:

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

Patients with liver or kidney problems or troublesome side effects:

Your doctor may reduce your dose to 2 mg Tolthen XL daily.

Use in children:

Tolthen XL is not recommended for children.

If you take more Tolthen XL 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 Tolthen XL

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 dose.

If you stop taking Tolthen XL

Your doctor will tell you how long your treatment with Tolthen XL 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 (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 tolterodine with the following frequencies:

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

- Dry mouth

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

- 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 (occurs in less than 1 in 100 patients) are:

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tolthen XL

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 of the outer carton, the blister and the bottle after "EXP". 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 Tolthen XL contains

The active substance in Tolthen XL 2 mg prolonged-release capsules, hard is 2 mg of tolterodine tartrate, equivalent to 1.37 mg of tolterodine.

The active substance in Tolthen XL 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, 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 Tolthen XL looks like and contents of the pack

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

Tolthen XL 2 mg prolonged-release hard capsules are opaque green-opaque green size 1 hard gelatin capsules containing two white, round, biconvex coated tablets.

Tolthen XL 4 mg prolonged-release hard capsules are light blue opaque-light blue opaque size 1 hard gelatin capsules containing four white, round, biconvex coated tablets.

Tolthen XL 2 mg prolonged-release hard capsules are available in the following pack sizes:

Blister packs containing: 14, 28, 30, 50, 84, 100 prolonged-release hard capsules
HPDE bottles containing: 30, 100 and 200 prolonged-release hard capsules

Tolthen XL 4 mg prolonged-release hard capsules are available in the following pack sizes:

Blister packs containing: 7, 14, 28, 49, 84, 98 prolonged-release hard capsules

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

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder:

Northumbria Pharma Ltd.
NETPark
Thomas Wright Way
Sedgefield
County Durham
TS21 3FD
United Kingdom

Manufacturer:

Pharmathen S.A
6, Dervenakion Str., Pallini Attiki, 153 51, Greece

or

Pharmathen International S.A
Sapes Industrial Park, Block 5, Rodopi, 69300, Greece

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