Package leaflet: Information for the user

Tolzurin 2 mg prolonged-release capsules, hard
Tolzurin 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 Tolzurin is and what it is used for

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

Do not take Tolzurin if you:
- are allergic to tolterodine or any of the other ingredients of this medicine
- are unable to pass urine from the bladder (urinary retention)
- have an uncontrolled high pressure in the eyes with loss of eyesight that is not being adequately treated (narrow-angle glaucoma)
- suffer from excessive weakness of the muscles (myasthenia gravis)
- suffer from severe ulceration and inflammation of the colon (ulcerative colitis)
- suffer from an acute dilatation of the colon (toxic megacolon).

Warnings and precautions
Talk to your doctor or pharmacist before taking Tolzurin:
- 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:
        - weak heart muscle (cardiomyopathy),
        - reduced blood flow to the heart (myocardial ischaemia),
        - irregular heartbeat (arrhythmia)
        - and heart failure
- If you have abnormally low levels of potassium (hypokalaemia), calcium (hypocalcaemia) or magnesium (hypomagnesaemia) in your blood.

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

Tolterodine, the active substance of Tolzurin, may interact with other medicines.

It is not recommended to use tolterodine in combination with:
- some antibiotics (containing e.g. erythromycin, clarithromycin)
- medicines used for the treatment of fungal infections (containing e.g. ketoconazole, itraconazole)
- medicines used for the treatment of HIV.

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

Tolzurin with food and drink
Tolzurin 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 Tolzurin when you are pregnant.

Breast-feeding
It is not known if tolterodine, the active substance of Tolzurin, is excreted in the mother's breast milk.

Breast-feeding is not recommended during administration of Tolzurin.

Driving and using machines
Tolzurin may make you feel dizzy, tired or affect your sight; your ability to drive or operate machinery may be affected.

Tolzurin 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.

Tolzurin contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Tolzurin

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 one 2 mg Tolzurin daily.

Use in children:
Tolzurin is not recommended for children.

If you take more Tolzurin than you should
If you or somebody else takes too many prolonged-release capsules, contact your doctor or pharmacist immediately.

If you forget to take Tolzurin
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 Tolzurin
Your doctor will tell you how long your treatment with Tolzurin 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 an allergic reaction, such as:

- swollen face, tongue or throat
- difficulty to swallow
- hives and difficulty in 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: may affect more than 1 in 10 people

- Dry mouth

Common: may affect up to 1 in 10 people

- Inflammation of nasal sinus (sinusitis)
- Dizziness, sleepiness, headache
- Dry eyes, blurred vision
- Indigestion (dyspepsia), constipation, abdominal pain, excessive amount of air or gases in the stomach or the intestine
- Painful or difficult urination
- Tiredness
- Extra fluid in the body causing swelling (e.g. in the ankles)
- Diarrhoea

Uncommon: may affect up to 1 in 100 people

- Allergic reactions
- Nervousness
- Sensation of pins and needles in the fingers and toes
- Vertigo

- Palpitations, heart failure, irregular heartbeat
- Inability to empty the bladder
- Chest pain
- Memory impairment

Additional reactions reported include severe allergic reactions, confusion, hallucinations, increased heart rate, flushed skin, heart burn, vomiting, severe swelling of the deeper layers of the skin, especially around the lips, eyes, genitals, hands, feet or tongue (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 to Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warszawa,
tel.: + 48 22 49 21 301, faks: + 48 22 49 21 309, strona internetowa: https://smz.ezdrowie.gov.pl.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tolzurin

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 carton, blister and 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 Tolzurin contains

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

The active substance in Tolzurin 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 Tolzurin looks like and contents of the pack

Tolzurin is a hard prolonged-release capsule designed for once daily dosing.
Tolzurin 2 mg prolonged-release hard capsules are opaque green-opaque green size 1 hard gelatin capsules containing two white, round, biconvex coated tablets.
Tolzurin 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.

Tolzurin 2 mg prolonged-release hard capsules are available in the following pack sizes:
Blister packs containing: 14, 28, 56, 84 prolonged-release hard capsules
HPDE bottles containing: 30, 100 and 200 prolonged-release hard capsules

Tolzurin 4 mg prolonged-release hard capsules are available in the following pack sizes:
Blister packs containing: 7, 14, 28, 49, 56, 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:
Recordati Polska sp. z o.o.
ul. Królewska 16
00-103 Warszawa

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

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

RAFARM SA
Thesi Pousi-Xatzi Agiou Louka, Paiania Attiki, 19002, Greece

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

UK (Northern Ireland)	Neditol XL 2mg, 4mg prolonged release capsules
CY	Tolterana 2mg, 4mg prolonged release capsules

DE	Tolterodin PUREN 4 mg Hartkapseln, retardiert
ES	Tolterodina Neo Edigen 4mg cápsulas duras de liberación prolongada EFG
PL	Tolzurin
EL	Toldesor 2mg, 4mg prolonged release capsules

This leaflet was last revised in 10/2022