

PACKAGE LEAFLET: INFORMATION FOR THE USER

Neditol XL 2mg prolonged-release capsules, hard Neditol XL 4mg 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 Neditol XL is and what it is used for
2. What you need to know before you take Neditol XL
3. How to take Neditol XL
4. Possible side effects
5. How to store Neditol XL
6. Contents of the pack and other information

1. What Neditol XL is and what it is used for

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

Neditol 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 Neditol XL

Do not take Neditol XL 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 acute dilatation of the colon (a toxic megacolon).

Warnings and Precautions

Talk to your doctor or pharmacist before taking Neditol 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: a weak heart muscle (cardiomyopathy), reduced blood flow to the heart (myocardial ischaemia), an 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 Neditol XL

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

Tolterodine, the active substance of Neditol XL, 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.

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

Neditol XL with food and drink

Neditol 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 Neditol XL when you are pregnant.

Breast-feeding

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

Driving and using machines

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

Neditol 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.

Neditol XL contains sodium

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

3. How to take Neditol 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 4mg prolonged-release hard capsule daily.

Patients with liver or kidney problems or troublesome side effects:

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

Use in children:

Neditol XL is not recommended for children.

If you take more Neditol XL 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 Neditol 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 Neditol XL

Your doctor will tell you how long your treatment with Neditol 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 an allergic reaction, such as:

- swollen face, tongue or throat.
- difficulty to swallow.
- hives and difficulty in 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 tolterodine with the following frequencies.

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

- Dry mouth

Common side effects (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 side effects (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 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 Neditol 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 carton and blister or 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 Neditol XL contains

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

The active substance in Neditol XL 4mg prolonged-release capsules, hard is 4mg of tolterodine tartrate, equivalent to 2.74mg of tolterodine.

The other ingredients are: lactose monohydrate, cellulose microcrystalline, poly(vinyl acetate), povidone, silica, sodium lauryl sulphate, sodium docusate, magnesium stearate, hydroxypropylmethylcellulose.

Capsule composition: indigo carmine (E132), quinoline yellow (only in 2mg) (E104), titanium dioxide (E171), gelatin.

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

What Neditol XL looks like and contents of the pack

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

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

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

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

Blister packs containing: 14, 28, 56, 84 prolonged-release hard capsules.

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

Neditol XL 4mg 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.

HDPE 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:

Aspire Pharma Ltd
Unit 4, Rotherbrook Court
Bedford Road, Petersfield
Hampshire, GU32 3QG, United Kingdom

Manufacturer:

Pharmathen SA
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Pallini, Attiki, Greece

or

Pharmathen International SA.,
Sapes Industrial Park, Block 5,
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