



PACKAGE LEAFLET: INFORMATION FOR THE USER

MORNINGSIDE  
HEALTHCARE

# Tolterodine Tartrate Morningside XL

2 mg and 4 mg Prolonged-Release Capsules

## 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 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 Tolterodine Capsules are and what they are used for
2. What you need to know before you take Tolterodine Capsules
3. How to take Tolterodine Capsules
4. Possible side effects
5. How to store Tolterodine Capsules
6. Contents of the pack and other information

### 1. What Tolterodine Capsules are and what they are used for

The active substance in Tolterodine Tartrate Morningside XL 2 mg and 4 mg Prolonged-Release Capsules is tolterodine. Tolterodine belongs to a class of medicinal products called antimuscarinics.

Tolterodine Capsules are 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 Tolterodine Capsules

#### Do not take Tolterodine Capsules 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 Tolterodine Capsules 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 neuronal disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system).
- have a hiatal 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 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.
- 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 Tolterodine Capsules if you think any of these might apply to you.

#### Other medicines and Tolterodine Capsules

Tolterodine, the active substance of Tolterodine Capsules, 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.

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

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

#### Tolterodine Capsules with food and drink

Tolterodine Capsules can be taken before, after or during a meal.

#### Pregnancy and breast-feeding

##### Pregnancy

You should not use Tolterodine Capsules 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 Tolterodine Capsules, is excreted in the mother's breast milk. Breast-feeding is not recommended during administration of Tolterodine Capsules.

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

#### Driving and using machines

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

#### Tolterodine Capsules contain sucrose

This medicine contains sucrose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### 3. How to take Tolterodine Capsules

#### Dosage

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 4 mg prolonged-release capsule daily, except for patients who have a kidney or a liver condition or troublesome side effects, in which case your doctor may reduce your dose to one 2 mg prolonged-release capsule daily. Tolterodine Capsules are not recommended for children.

The prolonged-release 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 Tolterodine Capsules 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.

#### If you have taken more Tolterodine Capsules 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 Tolterodine Capsules**

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 Tolterodine Capsules**

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 Tolterodine Capsules 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
- 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
- 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) are:

- 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, 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 at: [www.mhra.gov.uk/yellowcard](http://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 Tolterodine Capsules**

Keep this medicine out of the sight and reach of children.

Do not take Tolterodine Capsules after the expiry date which is stated on the label/carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Tolterodine Capsules contain**

The active substance in Tolterodine Tartrate Morningside XL 2 mg Prolonged-Release Capsules is 2 mg of tolterodine tartrate, equivalent to 1.37 mg of tolterodine and Tolterodine Tartrate Morningside XL 4 mg Prolonged-Release Capsules is 4 mg of tolterodine tartrate, equivalent to 2.74 mg of tolterodine.

The other ingredients are:

**Capsule contents:** sugar spheres (containing sucrose and maize starch), hypromellose, ethyl cellulose dispersion type B and talc.

**Capsule shell:** gelatin and colourants.

**Colourants:**

- Blue-green 2 mg prolonged-release capsule: iron oxide red, iron oxide yellow, titanium dioxide and FD & C blue 1.
- Blue 4 mg prolonged-release capsule: iron oxide red, titanium dioxide and FD & C blue 1.

**Printing ink:** shellac, titanium dioxide and propylene glycol (E1520).

**What Tolterodine Capsules look like and contents of the pack**

Tolterodine Capsules are hard prolonged-release capsules designed for once daily dosing.

Tolterodine Tartrate Morningside XL 2 mg Prolonged-Release Capsules are blue-green and marked with white printing (symbol 'L32' and 2).

Tolterodine Tartrate Morningside XL 4 mg Prolonged-Release Capsules are blue and marked with white printing (symbol 'L33' and 4).

Tolterodine Capsules are available in are available in Alu-Alu blister packs of 7, 14, 28, 30, 50, 56, 60, 84, 98, 100 and 280 capsules. Hospital packs are available in blister packs of 80, 160 and 320 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Morningside Healthcare Ltd.  
Unit C, Harcourt Way  
Leicester, LE19 1WP  
UK

**Manufacturer**

Morningside Pharmaceuticals Ltd.  
5 Pavilion Way, Castle Business Park  
Loughborough, LE11 5GW  
UK

**This leaflet was last revised in December 2021.**

