

**Package leaflet: Information for the patient**

Tolterodine tartrate 2mg/5ml Oral Suspension  
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. Do not pass it on to others. It may harm them, even if their symptoms 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.

The name of your medicine is Tolterodine tartrate 2mg/5ml Oral Suspension but it will be referred to as 'Tolterodine tartrate' throughout this leaflet.

**What is in this leaflet**

1. What Tolterodine tartrate is and what it is used for
2. What you need to know before you take Tolterodine tartrate
3. How to take Tolterodine tartrate
4. Possible side effects
5. How to store Tolterodine tartrate
6. Contents of the pack and other information

**1. What Tolterodine tartrate is and what it is used for**

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

**Do not take Tolterodine tartrate if:**

- You are allergic (hypersensitive) to tolterodine or any of the other ingredients in Tolterodine tartrate (listed in section 6).
- You are unable to pass urine from the bladder (urinary retention)
- You have an uncontrolled narrow-angle glaucoma (high pressure in the eyes with loss of eyesight that is not being adequately treated)
- You suffer from myasthenia gravis (excessive weakness of the muscles)
- You suffer from severe ulcerative colitis (ulceration and inflammation of the colon)
- You suffer from a toxic megacolon (acute dilatation of the colon).

**Warnings and precautions**

Talk to your doctor or pharmacist before you take Tolterodine tartrate if:

- You have difficulties in passing urine and/or a poor stream of urine
- You have a gastro-intestinal disease that affects the passage and/or digestion of food
- You suffer from kidney problems (renal insufficiency)

- You have a liver condition
- You suffer from neuronal disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system)
- You have a hiatal hernia (herniation of an abdominal organ)
- You ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility)
- You have abnormally low levels of potassium (hypokalaemia), calcium (hypocalcaemia) or magnesium (hypomagnesaemia) in your blood
- 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

#### **Other medicines and Tolterodine tartrate**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines as tolterodine 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 tartrate 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 (antimuscarinic properties) or medicines with an opposite mode of action to tolterodine (cholinergic properties). Ask your doctor if you are unsure.

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

#### **Tolterodine tartrate with food and drink**

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

#### **Pregnancy and breast-feeding**

##### **Pregnancy**

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

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

### **Driving and using machines**

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

### **Tolterodine tartrate contains methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium, benzyl alcohol and benzoic acid**

Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216): May cause allergic reactions (possibly delayed).

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

Benzoic acid (E210): This medicine contains 0.011 mg benzoic acid in each ml.

Benzyl alcohol (E1519): This medicine contains 0.02 mg benzyl alcohol in each ml. Benzyl alcohol may cause allergic reactions

## **3. How to take Tolterodine tartrate**

### **Dosage**

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

The usual dose is 2 mg (5 ml) twice 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 1 mg (2.5 ml) twice daily.

Tolterodine tartrate is not recommended for children.

Tolterodine tartrate is for oral use.

### **Duration of treatment**

Your doctor will tell you how long your treatment with Tolterodine tartrate 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 Tolterodine tartrate prescribed by your doctor. If you have not noticed any effect by then, talk to your doctor.

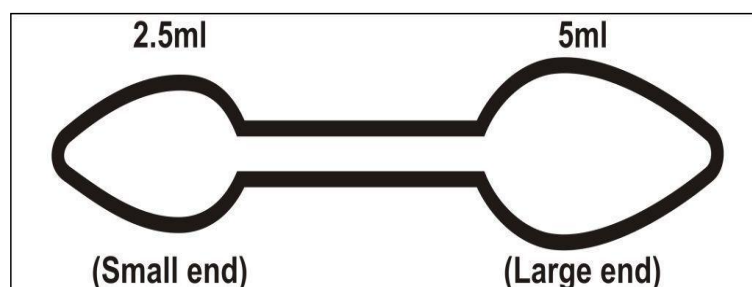
The benefit of the treatment should be re-evaluated after 2 or 3 months.

**Always consult your doctor if you are thinking of stopping the treatment.**

### **Route and Method of administration:**

- This medicinal product must be taken orally.
- Use the 2.5-5 ml double-ended spoon supplied in the pack to measure the required dose (see figure below).
- Shake well before use for at least 10 seconds.
- Wash the spoon with clean water after taking every dose.

### **2.5-5 ml double-ended Spoon**



**If you have taken more Tolterodine tartrate than you should:**

If you or somebody else takes too much Tolterodine tartrate, contact your doctor or pharmacist immediately.

**If you forget to take Tolterodine tartrate**

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, this medicine can cause side effects, although not everybody gets them.

You should see your doctor immediately or go to the Accident and Emergency 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 Accident and Emergency 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
- Headache

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

- Bronchitis
- Dizziness, sleepiness, sensation of pins and needles in the fingers and toes
- Dry eyes, blurred vision
- Vertigo
- Palpitations
- Difficulty in digestion (dyspepsia), constipation, abdominal pain, excessive amounts of air or gases in the stomach or the intestine, vomiting
- Dry skin
- Painful or difficult urination, inability to empty the bladder
- Tiredness, chest pain, extra fluid in the body causing swelling (e.g. in the ankles)
- Increased weight

- Diarrhoea

**Uncommon side effects** (occurs in less than 1 in 100 patients) are:

- Allergic reactions
- Nervousness
- Increased heart rate, heart failure, irregular heartbeat
- Heart burn
- Memory impairment

Additional reactions reported include severe allergic reactions, confusion, hallucinations, flushed skin, angioedema, 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](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 tartrate**

- 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 bottle label after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not refrigerate or freeze.
- Store in the original package to protect from light.
- Do not use this medicine if you notice that the suspension becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- 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 tartrate contains**

The active substance is tolterodine tartrate.

Each 5ml of oral suspension contains 2mg of tolterodine tartrate, equivalent to 1.37 mg tolterodine.

The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), simethicone emulsion 30% (contains benzoic acid (E210)), microcrystalline cellulose (E460), sucralose (E955), cherry flavour (contains propylene glycol (E1520) & benzyl alcohol (E1519)), silica colloidal anhydrous (E551), citric acid monohydrate (E330), sodium citrate (E331) and purified water.

#### **What Tolterodine tartrate looks like and contents of the pack**

Tolterodine tartrate is a white to off-white oral suspension in a glass bottle. Each pack contains one bottle containing 150 ml oral suspension and a 2.5-5 ml double ended spoon.

#### **Marketing Authorisation Holder and Manufacturer:**

Syri Limited t/a SyriMed  
Unit 4, Bradfield Road,  
Ruislip, Middlesex,  
HA4 0NU, UK.

**If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.**

**This leaflet was last revised in 12/2025.**