Package leaflet: Information for the patient

Tolterodine tartrate 0.4 mg/ml 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 0.4 mg/ml oral suspension but it will be referred to as 'Tolterodine tartrate oral suspension' throughout this leaflet.

What is in this leaflet

1. What Tolterodine tartrate oral suspension is and what it is used for
The active substance in Tolterodine tartrate oral suspension is tolterodine. Tolterodine belongs to a class of medicinal products called antimuscarinics. Tolterodine tartrate oral suspension 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 oral suspension

Do not take Tolterodine tartrate oral suspension if:
- You are allergic (hypersensitive) to tolterodine or any of the other ingredients in Tolterodine tartrate oral suspension (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 oral suspension 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 oral suspension
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 oral suspension 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 oral suspension with food and drink
Tolterodine tartrate oral suspension can be taken before, after or during a meal.

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

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

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

Tolterodine tartrate oral suspension 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 oral suspension

Dosage
Always take Tolterodine tartrate oral suspension 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 oral suspension is not recommended for children.

Tolterodine tartrate oral suspension is for oral use.

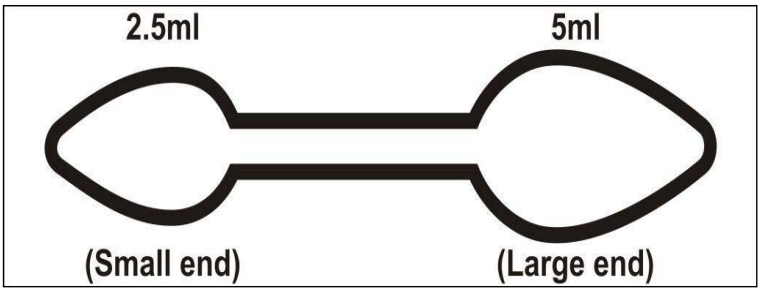
Duration of treatment
Your doctor will tell you how long your treatment with Tolterodine tartrate oral suspension will last. Do not stop treatment early because you do not see an immediate effect. Your bladder will need some time to adapt. Finish the course of Tolterodine tartrate oral suspension prescribed 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 oral suspension than you should:
If you or somebody else takes too much Tolterodine tartrate oral suspension, contact your doctor or pharmacist immediately.

If you forget to take Tolterodine tartrate oral suspension
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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tolterodine tartrate oral suspension

- 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 oral suspension contains
The active substance is tolterodine tartrate.
Each ml of oral suspension contains 0.4 mg of tolterodine tartrate.

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 oral suspension looks like and contents of the pack
Tolterodine tartrate oral suspension 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:
Syri Pharma Limited t/a Thame Laboratories
Floor 0, 1 WML,
1 Windmill Lane
Dublin 2, D02 F206, Ireland

Manufacturer:
Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola PLA 3000, Malta.

This medicine is authorised in the Member States of the European Economic Area under the following name:
NL: Tolterodinetartraat Syri pharma 0,4 mg/ml, suspensie voor oraal gebruik
IE: Tolterodine tartrate 0.4 mg/ml oral suspension

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in 09/2025.