Package leaflet: Information for the patient

Tolterodine tartrate 1 mg film-coated tablets
Tolterodine tartrate 2 mg film-coated tablets
tolterodine-L-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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

Tolterodine tartrate 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 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).

Warning and precautions

Talk to your doctor, pharmacist or nurse before taking Tolterodine tartrate:

- 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 impairment)
- if you suffer from any liver disease.

- if you suffer from neuronal disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system)
- if you have a hiatal 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:
        - cardiomyopathy (weak heart muscle)
        - myocardial ischaemia (reduced blood flow to the heart)
        - arrhythmia (irregular heartbeat)
        - and heart failure
- if you 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 tartrate Film-coated Tablets if you think any of these might apply to you.

Other medicines and Tolterodine tartrate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Tolterodine tartrate may interact with other medicinal products.

It is not recommended to use tolterodine tartrate 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.

Tolterodine tartrate with food and drink

There are no special instructions.
Tolterodine tartrate can be taken either before, during or after 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 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 is excreted into the mother's breast milk. Breast-feeding is not recommended during administration of Tolterodine tartrate.

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

3. How to take Tolterodine tartrate

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

Dosage

The recommended dose is one 2 mg tablet 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 one 1 mg tablet twice daily.

Tolterodine tartrate is not recommended for children.

The tablets are for oral use and should be swallowed whole.

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 tablets 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 take more Tolterodine tartrate than you should
If you or somebody else have taken too many tablets, contact your doctor or go to the nearest hospital.

If you forget to take Tolterodine tartrate
If you have forgotten to take Tolterodine, take it as soon as you remember, unless it is time for the 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 Tolterodine tartrate
Before stopping to take the medicine, please consult your doctor.
Currently there is no known negative effect due to abrupt withdrawal of the medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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 tartrate with the following frequencies.

Very common (may affect more than 1 in 10 people) are dry mouth and headache.

Common (may affect up to 1 in 10 people)

- 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 (may affect up to 1 in 100 people)

- Allergic reactions
- Nervousness
- Increased heart rate, heart failure, irregular heartbeat
- Gastroesophageal reflux (stomach acid coming up from the stomach into oesophagus with typical symptom - heartburn)
- Memory impairment

Not known (frequency cannot be estimated from the available data)

- 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 side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Tolterodine tartrate film-coated tablets

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 label/carton. The expiry date refers to the last day of that month..

This medicine 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 tartrate **contains**
Tolterodine tartrate 1 mg film-coated tablets
The active substance is 1 mg of tolterodine-L-tartrate (0.68 mg tolterodine base) in each film-coated tablet..

Tolterodine tartrate 2 mg film-coated tablets
The active substance is 2 mg of tolterodine-L-tartrate (1.37 mg tolterodine base) in each film-coated tablet..

The other ingredients are:
Sodium starch glycolate (Type B), microcrystalline cellulose, colloidal anhydrous silica, calcium hydrogen phosphate dihydrate, magnesium stearate, partially hydrolysed polyvinyl alcohol, titanium dioxide E171, talc, and macrogol.

What Tolterodine tartrate looks like and contents of the pack

Tolterodine tartrate 1 mg film-coated tablets
White to off-white, round film-coated tablets debossed with ‘93’ on one side and ‘10’ on the other side.

Tolterodine tartrate 2 mg film-coated tablets
White to off-white, round film-coated tablets debossed with ‘93’ on one side and ‘18’ on the other side.

Transparent PVC/PVdC-aluminium blister package and cardboard box

Tolterodine tartrate 1 mg film-coated tablets

14, 20, 28, 30, 50, 56, 60, 90 and 100 film-coated tablets in blisters. Hospital: 50, 60, 250, 280, 500 and 560 film-coated tablets.

Tolterodine tartrate 2 mg film-coated tablets
14, 20, 28, 30, 50, 56, 60, 90 and 100 film-coated tablets in blisters. Hospital: 50, 280 and 560 film-coated tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
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