Package leaflet: Information for the user

Tolterodine tartrate 1 mg & 2 mg film-coated tablets
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 Tolterodine tartrate is and what it is used for

Tolterodine tartrate contains the active substance 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 of this medicine (listed in section 6)
- If you are unable to pass urine from the bladder (urinary retention)
- If you have an uncontrolled narrow-angle glaucoma (high pressure in the eyes with loss of eyesight that is not being adequately treated)
- If you suffer from myasthenia gravis (excessive weakness of the muscles)
- If you suffer from severe ulcerative colitis (ulceration and inflammation of the colon)
- If you suffer from a toxic megacolon (acute dilatation of the colon).

Warnings and precautions

Talk to your doctor or pharmacist 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 insufficiency)
- If you have a liver condition
- 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

Children and adolescents
Efficacy of Tolterodine tartrate has not been demonstrated in children. Therefore, Tolterodine tartrate is not recommended for children.

Other medicines and Tolterodine tartrate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tolterodine, the active substance of Tolterodine tartrate, 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 tartrate (antimuscarinic properties) or medicines with an opposite mode of action to Tolterodine tartrate (cholinergic properties).

Tolterodine tartrate with food and drink
Tolterodine tartrate 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 Tolterodine tartrate when you are 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.

Tolterodin Pfizer contains sodium
Tolterodin Pfizer contains less than 1 mmol sodium (23 mg) per 1 mg and 2 mg film-coated tablets, 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.

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.

Method of administration:
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.

If you take more Tolterodine tartrate than you should:
If you or somebody else takes too many tablets, 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 dose.

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 tartrate with the following frequencies.

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

- Dry mouth
- 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 with 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
- 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. 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, bottle label and blister after EXP. The expiry date refers to the last day of that month.

No special precautions for storage.

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.

Each film-coated tablet contains 1 mg tolterodine tartrate, equivalent to 0.68 mg of tolterodine.

The active substance is tolterodine.

Each film-coated tablet contains 2 mg of tolterodine tartrate, equivalent to 1.37 mg of tolterodine.

The other ingredients are:
Core: Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium starch glycollate (Type B) (see section 2 "Tolterodine Pfizer contains sodium"), magnesium stearate and colloidal anhydrous silica.

Film coating: Hypromellose, microcrystalline cellulose, stearic acid and titanium dioxide (E171).

What Tolterodine tartrate looks like and contents of the pack

Tolterodine tartrate 1 mg film-coated tablets are white, round, biconvex and marked with arcs above and below the lettering TO.

Tolterodine tartrate 2 mg film-coated tablets are white, round, biconvex and marked with arcs above and below the lettering DT.

Tolterodine tartrate 1 mg and 2 mg film-coated tablets are available in the following pack sizes:
Blister packs containing 14, 20, 28, 30, 50, 56, 98, 100, 280 or 560 tablets.

Bottles containing 60 or 500 tablets.
Not all pack sizes may be marketed.

Marketing authorisation holder and Manufacturer
Marketing authorisation holder:
Upjohn UK Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
United Kingdom

Manufacturer:
Pfizer Italia S.r.l
Località Marino del Tronto
63100 Ascoli Piceno
Italy

This medicinal product is authorised in the following Member States of the EEA under the trade name:
Tolterodine Pfizer: Belgium, France, Luxembourg, Netherlands
Tolterodin Pfizer: Austria, Finland, Sweden

Tolterodina Pharmacia: Spain
Santizor: Greece
Tolterodine tartrate (1 mg/2 mg) film-coated tablets: UK

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