PACKAGE LEAFLET: INFORMATION FOR THE USER

Tolterodine tartrate 1mg film-coated tablets
Tolterodine tartrate 2mg 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 further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. 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.

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

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, that 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 in this medicine (see section 6. "Further information").
- If you are unable to pass urine from the bladder (urinary retention).
- If you have an increased eye pressure that is not being adequately treated (uncontrolled narrow angle glaucoma).
- If you suffer from a certain muscle weakness (myasthenia gravis).
- If you suffer from an ulceration and inflammation of the colon (severe ulcerative colitis).
- If you suffer from an acute dilation of the colon (toxic megacolon).

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 gastrointestinal disease that affects the passage and/or digestion of food.
- If you suffer from kidney problems.
- If you have a liver condition.
- If you suffer from neuronal disorders that affect your blood pressure, bowel or sexual function (autonomic neuropathy).
- If a part of your stomach protrudes through the diaphragm (hiatus hernia).
- If you experienced decreased bowel movements or suffer from severe constipation.
- If you have a heart condition such as:
  - an abnormal heart tracing (ECG)
  - a slow heart rate (bradycardia)
  - relevant pre-existing cardiac diseases (weak heart muscle [cardiomyopathy], reduced blood flow to the heart [myocardial ischaemia], irregular heartbeat [arrhythmia] and heart failure).
- If you have abnormally low levels of potassium, calcium or magnesium in your blood.
- If you are taking any medicine for the treatment of an irregular heartbeat (see "Other medicines and Tolterodine tartrate").

Ask your doctor or pharmacist before starting treatment with Tolterodine tartrate if you think any of these might apply to you.

Other medicines and Tolterodine tartrate

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

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 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 medicinal products with a similar mode of action to Tolterodine tartrate (antimuscarinic properties) or with an opposite mode of action to Tolterodine tartrate (cholinergic properties).

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 in the mother's breast milk. Breast-feeding is not recommended while taking this 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 lactose:

If you have been told that you have an intolerance to some sugars speak to your doctor before taking Tolterodine tartrate.

Tolterodine tartrate contains sodium

This medicine contains less than 1mmol sodium (23mg) per 1mg and 2mg film-coated tablets, that is to say essentially "sodium-free".

3. HOW TO TAKE TOLTERODINE TARTRATE

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

Adults

The recommended dose is 2mg twice daily. If you have liver or kidney problems, your doctor may reduce your dose to one 1mg tablet twice daily.

Tolterodine tartrate is not recommended for children.

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

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

If you take more Tolterodine tartrate than you should:

If you or somebody else takes too many tablets, contact your doctor or pharmacist immediately.

Symptoms in case of overdose include convulsions, hallucinations, excitation, a heartbeat faster than usual, dilation of the pupil and inability to urinate or breathe normally.

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 the forgotten dose.

If you stop taking Tolterodine tartrate

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 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 casualty department if you experience symptoms of angioedema (allergic reaction), such as:

- swollen face, tongue or pharynx
- difficulty swallowing
- hives and difficulty in breathing

This occurs uncommonly (occurs in less than 1 in 100 patients).

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 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 (occurs in less than 1 in 100 patients).

The following side effects have been observed during treatment with Tolterodine tartrate with the following frequencies.

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

- Dry mouth
- Headache

Common side effects *(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 side effects *(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 of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. 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

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.

No special precautions for storage.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tolterodine tartrate contains

The active substance is Tolterodine L-tartrate.

Each 1mg film-coated tablet contains 1mg tolterodine L-tartrate (equivalent to 0.68mg of tolterodine).

Each 2mg film-coated tablet contains 2mg tolterodine L-tartrate (equivalent to 1.37mg of tolterodine).

The other ingredients are:

Core: Microcrystalline cellulose, dibasic calcium phosphate dihydrate, sodium starch glycolate, silica colloidal anhydrous, magnesium stearate.

Film-coating: Hypromellose, lactose monohydrate, polyethylene glycol, titanium dioxide (E171).

What Tolterodine tartrate looks like and contents of the pack

Tolterodine tartrate 1mg film-coated tablets are white, round biconvex film-coated tablets, embossed with "1" on one side.

Tolterodine tartrate 2mg film-coated tablets are white, round biconvex film-coated tablets, embossed with "2" on one side and with a score line on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

PVC/PE/PVDC Aluminium blister:

Pack sizes of 14, 20, 28, 30, 50, 56, 60 and 100 film-coated tablets.

HDPE tablet container with a child-resistant PP screw cap:

Pack sizes of 60 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Aspire Pharma Ltd
Unit 4, Rotherbrook Court, Bedford Rd
Petersfield, Hampshire,
GU32 3QG, United Kingdom

Manufacturers:

Pharmathen S.A
6, Dervenakion Str., 153 51 Pallini Attiki, Greece
and
Pharmathen International S.A
Sapes Industrial Park, Block 5, 69300 Rodopi, Greece

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