PACKAGE LEAFLET: INFORMATION FOR THE USER
Tolterodine Tartrate 1 mg Film-coated Tablet
Tolterodine Tartrate 2 mg Film-coated Tablet
Tolterodine tartrate

Read all of this leaflet carefully before you start using 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 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

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

Tolterodine 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 (hypersensitive) to tolterodine or any of the other ingredients in the 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).

Warning and precautions
- 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)
    - 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 if you think any of these might apply to you.

Other medicines and Tolterodine Tartrate

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

Tolterodine, the active substance of 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 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

This medicine can be taken before, after or during a meal.

Pregnancy and breast-feeding

Pregnancy

You should not use tolterodine 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 during administration of tolterodine.

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

Driving and using machines

Tolterodine 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 tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE TOLTERODINE TARTRATE

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

The usual 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 have taken more Tolterodine Tartrate than you should:

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

In case of tolterodine overdose, the following symptoms are reported.

- Severe central anticholinergic effects (e.g. hallucinations, severe excitation)
- Convulsions or pronounced excitation
- Respiratory insufficiency
- Tachycardia
- Urinary retention
- Mydriasis
- Increase in QT interval

If you forget to take Tolterodine Tartrate

Do not take a double dose to make up for a forgotten one. If you have forgotten to take a dose at the usual time, you can *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.

If you stop using Tolterodine Tartrate

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, tolterodine 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 (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 with the following frequencies.

Very common (occurs in more than 1 in 10 patients) side effects are:

- Dry mouth
- Headache

Common (occur in less than 1 per 10 patients) side effects are:

- Bronchitis
- Dry eyes
- Spinning sensation
- Bad digestion (dyspepsia)
- Painful or difficult urination
- Being sick (vomiting)
- Diarrhoea
- Dizziness
- Blurred vision
- Palpitations
- Constipation
- Increased weight
- Inability to empty the bladder
- Sleepiness
- Abdominal pain
- Dry skin
- Tiredness
- Chest pain
- Sensation of pins and needles in the fingers and toes
- Excessive amounts of air or gases in the stomach or the intestine

- Extra fluid in the body causing swelling (e.g. in the ankles)

Uncommon (occur in less than 1 per 100 patients) side effects are:

- Allergic reactions
- Increased heart rate
- Memorial impairment
- Nervousness
- Heart failure
- Irregular heartbeat
- Heart burn

Additional reactions reported from post marketing experience include severe allergic reactions, confusion, hallucinations (seeing, hearing, feeling, tasting or smelling things that are not there), flushing, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

For Ireland -
HPRA Pharmacovigilance
Website: www.hpra.ie

5. HOW TO STORE TOLTERODINE TARTRATE

Keep this medicine out of the sight and reach of children.

Do not use tolterodine film-coated tablets after the expiry date, which is stated on the label/carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

6. CONTENTS OF PACK AND OTHER INFORMATION

What Tolterodine Tartrate contains

The active substance is 1 mg of tolterodine tartrate, equivalent to 0.68 mg of tolterodine.

The active substance is 2 mg of tolterodine tartrate, equivalent to 1.37 mg of tolterodine.

The other ingredients are:

Core: Cellulose, microcrystalline; sodium starch glycolate (Type A); magnesium stearate; colloidal anhydrous silica

Film coating: Hypromellose (E464), titanium dioxide (E171), macrogol 8000, talc (E553b)

What Tolterodine Tartrate looks like and contents of the pack

Tolterodine Tartrate 1 mg film-coated tablets are white to off white, round, approximately 6.35 mm in diameter, biconvex, film-coated tablet, debossed S16 on one side and plain on other side.

Tolterodine Tartrate 2 mg film-coated fablets are white to off white, round, approximately 6.35 mm in diameter, biconvex, film-coated tablet, debossed S042 on one side and plain on other side.

Tolterodine Tartrate 1 mg film-coated tablets are available in the following pack sizes:
Tolterodine Tartrate 2 mg film-coated tablets are available in the following pack sizes:

Blister packs containing;

- 14 film-coated tablets (1 strip of 14)
- 28 film-coated tablets (2 strips of 14)
- 56 film-coated tablets (4 strips of 14)
- 20 film-coated tablets (2 strips of 10)
- 50 film-coated tablets (5 strips of 10)
- 100 film-coated tablets (10 strips of 10)
- 30 film-coated tablets (3 strips of 10 or 2 strips of 15)
- 60 film-coated tablets (6 strips of 10 or 4 strips of 15)
- 90 film-coated tablets (9 strips of 10 or 6 strips of 15)

Please note that not all the above pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing Authorisation Holder:

United Kingdom
Accord Healthcare Limited.
Sage house, 319 Pinner road,
North Harrow, HA1 4HF
United Kingdom

Ireland
Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer:
Accord Healthcare Limited.
Sage house, 319 Pinner road,
North Harrow, HA1 4HF
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Country	Proposed Name
Denmark	Tolterodintartrat Accord 1 / 2 mg filmovertrukne tabletter
Bulgaria	Tolterodine Accord 2 mg Film-coated Tablets
Cyprus	Tolterodine Accord 2 mg Film-coated Tablets
Estonia	Tolterodine Accord 1 / 2 mg
Latvia	Tolterodine Accord 1 / 2 mg Film-coated Tablets
Poland	Tolterodine Accord
Austria	Tolterodin Accord 1 mg/2 mg Filmtabletten
Germany	Tolterodin Accord 1 mg/2 mg Filmtabletten
France	Tolterodine Accord 1 mg/ 2 mg comprimé pelliculé
Ireland	Tolterodine Tartrate 1 mg/2 mg Film-coated Tablet
Netherlands	Tolterodinetartraat Accord 1 mg/2 mg filmomhulde tabletten
Sweden	Tolterodintartrat Accord 1 / 2 mg filmdragerade tabletter
UK	Tolterodine Tartrate 1 mg/2 mg Film-coated Tablet

This leaflet was last revised in 03/2021.