

## PACKAGE LEAFLET: INFORMATION FOR THE USER

---

### TOLDEX

4 mg prolonged-release capsules, hard

### TOLTERODINE

---

*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •*

---

#### What is in this leaflet?

1. What TOLDEX is and what it is used for
2. Before you take TOLDEX
3. How to take TOLDEX
4. Possible side effects
5. How to store TOLDEX

#### 1. WHAT TOLDEX IS AND WHAT IS IT USED FOR

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

TOLDEX 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. BEFORE YOU TAKE TOLDEX

##### **Do not take TOLDEX if you:**

- are allergic (hypersensitive) to tolterodine or any of the other ingredients in TOLDEX
- 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).

***Take special care with TOLDEX***

- 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.

Talk to your doctor or pharmacist before starting your treatment with TOLDEX if you think any of these might apply to you.

***Taking other medicines***

Tolterodine, the active substance of TOLDEX, 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.

TOLDEX 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 TOLDEX (antimuscarinic properties) or medicines with an opposite mode of action to TOLDEX (cholinergic properties).
- Ask your doctor if you are unsure.

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

### ***Taking TOLDEX with food and drink***

TOLDEX can be taken before, after or during a meal.

### ***Pregnancy and breast-feeding Pregnancy***

You should not use TOLDEX 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 TOLDEX, is excreted in the mother's breast milk. Breast-feeding is not recommended during administration of TOLDEX.

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

### ***Driving and using machines***

TOLDEX may make you feel dizzy, tired or affect your sight; your ability to drive or operate machinery may be affected.

***Important information about some of the ingredients of TOLDEX*** This medicine contains sucrose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

## ***3. HOW TO TAKE TOLDEX***

### **Dosage**

Always take TOLDEX 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 4 mg prolonged-release capsule 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 2 mg Detrusitol daily.

TOLDEX is not recommended for children.

The prolonged-release capsules are for oral use and should be swallowed whole. Do not chew the capsules.

### **Duration of treatment**

Your doctor will tell you how long your treatment with TOLDEX 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 prolonged-release capsules 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 TOLDEX than you should***

If you or somebody else takes too many prolonged-release capsules, contact your doctor or pharmacist immediately.

### ***If you forget to take TOLDEX***

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, TOLDEX 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 TOLDEX with the following frequencies.

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

- Dry mouth

**Common side effects** (occurs in less than 1 in 10 patients) are:

- Sinusitis
- Dizziness, sleepiness, headache
- Dry eyes, blurred vision
- Difficulty with digestion (dyspepsia), constipation, abdominal pain, excessive amounts of air or gases in the stomach or the intestine
- Painful or difficult urination
- Tiredness
- Extra fluid in the body causing swelling (e.g. in the ankles)
- Diarrhoea

**Uncommon side effects** (occurs in less than 1 in 100 patients) are:

- Allergic reactions
- Nervousness
- Sensation of pins and needles in the fingers and toes
- Vertigo
- Palpitations, heart failure, irregular heartbeat
- Inability to empty the bladder
- Chest pain
- Memory impairment

Additional reactions reported include severe allergic reactions, confusion, hallucinations, increased heart rate, flushed skin, heart burn, vomiting, angioedema, dry skin, 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. By reporting side effects you can help provide more information on the safety of this medicine.

***5. HOW TO STORE TOLDEX***

Keep TOLDEX out of the reach and sight of children.

Do not use TOLDEX after the expiry date which is stated on the label/carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Keep the blister in the outer carton.

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.