

PATIENT INFORMATION

**Tolterodine Tartrate Extended-release Capsules, USP
(tol ter’ oh deen tar’ trate)
2 mg and 4 mg**

Read the Patient Information that comes with tolterodine tartrate extended-release capsules before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or your treatment. Only your doctor can determine if treatment with tolterodine tartrate extended-release capsules is right for you.

What are tolterodine tartrate extended-release capsules?

Tolterodine tartrate extended-release capsules are a prescription medicine for **adults** used to treat the following symptoms due to a condition called **overactive bladder**:

- Having a strong need to urinate with leaking or wetting accidents (urge urinary incontinence).
- Having a strong need to urinate right away (urgency).
- Having to urinate often (frequency).

Tolterodine tartrate extended-release capsules did not help the symptoms of overactive bladder when studied in children.

What is overactive bladder?

Overactive bladder happens when you cannot control your bladder muscle. When the muscle contracts too often or cannot be controlled, you get symptoms of overactive bladder, which are leakage of urine (urge urinary incontinence), needing to urinate right away (urgency), and needing to urinate often (frequency).

Who should not take tolterodine tartrate extended-release capsules?

Do not take tolterodine tartrate extended-release capsules if:

- You have trouble emptying your bladder (also called “urinary retention”).
- Your stomach empties slowly (also called “gastric retention”).
- You have an eye problem called “uncontrolled narrow-angle glaucoma”.
- You are allergic to tolterodine tartrate extended-release capsules or to any of its ingredients. See the end of this leaflet for a complete list of ingredients.
- You are allergic to TOVIAZ, which contains fesoterodine.

What should I tell my doctor before starting tolterodine tartrate extended-release capsules?

Before starting tolterodine tartrate extended-release capsules, tell your doctor about all of your medical conditions, including if you:

- Have any stomach or intestinal problems.
- Have trouble emptying your bladder or you have a weak urine stream.
- Have an eye problem called narrow-angle glaucoma.
- Have liver problems.
- Have kidney problems.
- Have a condition called myasthenia gravis.
- Or any family members have a rare heart condition called QT prolongation (long QT syndrome).
- Are pregnant or trying to become pregnant. It is not known if tolterodine tartrate extended-release capsules could harm your unborn baby.
- Are breastfeeding. It is not known if tolterodine tartrate passes into your milk and if it can harm your child.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Other drugs can affect how your body handles tolterodine tartrate extended-release capsules. Your doctor may use a lower dose of tolterodine tartrate extended-release capsules if you are taking:

- Certain medicines for fungus or yeast infections such as Nizoral® (ketoconazole), Sporanox® (itraconazole), or Monistat® (miconazole).
- Certain medicines for bacteria infections such as Biaxin® (clarithromycin).
- Certain medicines for treatment of HIV infection such as Norvir® (ritonavir), Invirase® (saquinavir), Reyataz® (atazanavir).
- Sandimmune® (cyclosporine) or Velban® (vinblastine).

Know the medicines you take. Keep a list of them with you to show your doctor or pharmacist each time you get a new medicine.

How should I take tolterodine tartrate extended-release capsules?

- Take tolterodine tartrate extended-release capsules exactly as prescribed. Your doctor will prescribe the dose

that is right for you. Do not change your dose unless told to do so by your doctor.

- Take tolterodine tartrate extended-release capsules once a day with liquid. Swallow the whole capsule. Tell your doctor if you cannot swallow a capsule.
- Tolterodine tartrate extended-release capsules can be taken with or without food.
- Take tolterodine tartrate extended-release capsules the same time each day.
- If you miss a dose of tolterodine tartrate extended-release capsules, begin taking tolterodine tartrate extended-release capsules again the next day. Do not take 2 doses of tolterodine tartrate extended-release capsules in the same day.
- If you took more than your prescribed dose of tolterodine tartrate extended-release capsules, call your doctor or poison control center, or go to the hospital emergency room.

What are possible side effects of tolterodine tartrate extended-release capsules?

Tolterodine tartrate extended-release capsules may cause allergic reactions that may be serious. Symptoms of a serious allergic reaction may include swelling of the face, lips, throat, or tongue. If you experience these symptoms, you should stop taking tolterodine tartrate extended-release capsules and get emergency medical help right away.

The most common side effects with tolterodine tartrate extended-release capsules are:

- | | |
|-------------|----------------|
| • Dry mouth | • Constipation |
| • Headache | • Stomach pain |

Medicines like tolterodine tartrate extended-release capsules can cause blurred vision, dizziness, and drowsiness.

Do not drive, operate machinery or do other dangerous activities until you know how tolterodine tartrate extended release capsules affect you.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

These are not all the side effects with tolterodine tartrate extended-release capsules. For a complete list, ask your doctor or pharmacist.

How do I store tolterodine tartrate extended-release capsules?

- Store tolterodine tartrate extended-release capsules at room temperature, 68° - 77°F (20° - 25°C); brief periods permitted between 59° - 86°F (15° - 30°C). Protect from light. Keep in a dry place.
- **Keep tolterodine tartrate extended-release capsules and all medicines out of the reach of children.**

General Information about tolterodine tartrate extended-release capsules

Medicines are sometimes prescribed for conditions that are not in the patient information leaflet. Only use tolterodine tartrate extended-release capsules the way your doctor tells you. Do not share it with other people even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about tolterodine tartrate extended-release capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about tolterodine tartrate extended-release capsules that is written for health professionals. You can also call Inventia Healthcare Limited, at 1-800-270-7585.

What are the ingredients in tolterodine tartrate extended-release capsules?

Active ingredients: tolterodine tartrate USP

Inactive ingredients: colloidal silicon dioxide, dibutyl sebacate, ethylcellulose, FD & C Blue no. 2, gelatin, hypromellose, hypromellose phthalate, sucrose, talc and titanium dioxide. 2 mg capsule also contains Iron oxide yellow. Capsules have pharmaceutical grade printing ink that contains ammonium hydroxide, iron oxide black, shellac, potassium hydroxide, propylene glycol and titanium dioxide.

Manufactured By:
Inventia Healthcare Limited,
F1-F1/1-F75/1, Additional Ambernath MIDC,
Ambernath (East) - 421506
Dist.-Thane, Maharashtra, INDIA.

Distributed By:
ANI Pharmaceuticals, Inc.
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