

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Tolterodine E.R. Medomie 2 mg

Each extended-release capsule contains:
tolterodine tartrate 2 mg

Tolterodine E.R. Medomie 4 mg

Each extended-release capsule contains:
tolterodine tartrate 4 mg

Inactive ingredients and allergens in this medicine: see section 6 'Additional information' and section 2 under 'Important information about some of this medicine's ingredients'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

For the treatment of an overactive bladder, expressed as urinary frequency and urgency or urge incontinence.

Therapeutic group: Muscarinic receptor antagonist.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
- You have difficulty 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 sensitive to medicines that contain fesoterodine.

Special warnings about using this medicine

Before using Tolterodine E.R. Medomie, tell your doctor if:

- You have a stomach problem or digestive problems.
- You have difficulty emptying your bladder or have a weak stream of urine.
- You have an eye problem called "narrow-angle glaucoma".
- You have liver problems.
- You have kidney problems.
- You have a disease called myasthenia gravis.
- You or someone in your family has a rare heart problem called "prolonged QT interval" (long QT syndrome).
- You are pregnant or breast-feeding, planning to become pregnant or breast-feed - see 'Pregnancy and breast-feeding' section.

Children and adolescents

There is no information about the effectiveness of use of this medicine in children and adolescents.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Other medicines may affect the way your body handles Tolterodine E.R. Medomie. Your doctor may prescribe a lower dose if you are taking:

- Certain medicines for fungal infections such as ketoconazole, itraconazole, miconazole.
 - Certain medicines for bacterial infections such as clarithromycin.
 - Certain medicines for treatment of HIV infection such as ritonavir, saquinavir, atazanavir.
- You should know the medicines you take. Keep a list of the medicines so that you can show your doctor or pharmacist each time you receive a new medicine.

Using this medicine and food

The capsule may be taken with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you are pregnant or are planning to become pregnant, consult your doctor before taking this medicine. It is not known if Tolterodine E.R. Medomie can harm your unborn baby.

If you are breast-feeding or planning to breast-feed, consult your doctor before using this medicine. It is not known if Tolterodine E.R. Medomie passes into breast milk and whether it can harm your baby.

Driving and using machines

Do not drive, operate machines or perform other dangerous activities until you know how Tolterodine E.R. Medomie affects you. Antimuscarinic medicines such as Tolterodine E.R. Medomie may have side effects such as blurred vision, dizziness or sleepiness.

Important information about some of this medicine's ingredients

The capsule contains sucrose - if you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before beginning treatment.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose and how you should take this medicine.

Only your doctor will determine your dose and how you should take this medicine. Do not change your dose unless your doctor has told you to do so.

The recommended dosage is usually:

One capsule once a day with a glass of water. The capsule should be swallowed whole as it has an extended-release mechanism.

Tell your doctor if you cannot swallow capsules.

The capsule may be taken with or without food.

Take the capsule at the same time each day.

Do not exceed the recommended dose.

If you have accidentally taken a higher dose

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget to take this medicine at the scheduled time, take the next dose the next day. Do not take 2 doses of the medicine on the same day.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Tolterodine E.R. Medomie may cause side effects in some users. Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

Stop taking Tolterodine E.R. Medomie and seek medical assistance immediately if you experience any of the following symptoms:

Tolterodine E.R. Medomie may cause allergic reactions that can be severe. The symptoms of a severe allergic reaction may include swelling of the face, lips, throat or tongue, difficulty breathing, blockage of the upper respiratory tract or a drop in blood pressure.

The most common side effects are:

- Dry mouth
- Headache
- Constipation
- Abdominal pain

Additional side effects

Dizziness, indigestion, tiredness, dry eyes, blurred vision, sleepiness, anxiety, sinusitis, painful urination.

Severe allergic reaction (anaphylaxis) and subcutaneous oedema, fast heartbeat (tachycardia), palpitations, peripheral oedema (swelling of the limbs), diarrhoea, confusion, disorientation, memory impairment, hallucinations.

There have been reports of worsening symptoms of dementia (such as confusion, disorientation, delusions) after starting treatment with Tolterodine E.R. Medomie in patients taking cholinesterase inhibitors for the treatment of dementia.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store the medicine in the original package below 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Capsule contents: sugar spheres, ethylcellulose dispersion Type B, hydroxypropylmethyl cellulose, talc.

Capsule shell: gelatin, water, sodium lauryl sulfate.

Printing ink: shellac (E904), dehydrated alcohol (E1510), isopropyl alcohol, butyl alcohol, propylene glycol (E1520), strong ammonia solution (E527), purified water, potassium hydroxide (E525), titanium dioxide (E171).

Colourants:

2 mg: titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), FD & C Blue 1 (E133)

4 mg: titanium dioxide (E171), iron oxide red (E172), FD & C Blue 1 (E133)

Each Tolterodine E.R. Medomie 2 mg capsule contains 54.44 mg of sugar.

Each Tolterodine E.R. Medomie 4 mg capsule contains 108.88 mg of sugar.

What the medicine looks like and contents of the pack:

Tolterodine E.R. Medomie 2 mg – a blue-green capsule with “L 32” and “2” printed in white.

Tolterodine E.R. Medomie 4 mg – a blue capsule with “L 33” and “4” printed in white.

Each pack contains 28 capsules.

Registration holder's name and address:

Medomie Pharma Ltd., P.O.B. 742, Givatayim, 5310602, Israel.

Manufacturer's name and address:

Macleods Pharmaceuticals Limited
Block-N2, Village Theda,
Post Office Lodhimajra,
Tehsil Baddi, Distt. Solan,
Himachal Pradesh-174 101,
India

This leaflet was revised in April 2025.

Registration numbers of the medicine in the Ministry of Health's National Drug Registry:

Tolterodine E.R. Medomie 2 mg: 174-90-36958-99

Tolterodine E.R. Medomie 4 mg: 174-91-36959-99