This leaflet format has been determined by the Ministry of Health and the content thereof has been checked and approved

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Tolterodine ER Teva® 2 mg

Extended Release Capsules

Composition
Each Extended Release capsule contains:
Tolterodine tartrate 2 mg

Tolterodine ER Teva® 4 mg

Extended Release Capsules

Composition
Each Extended Release capsule contains:
Tolterodine tartrate 4 mg

For the list of inactive ingredients, see section 6 (Further information).

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass this medicine on to others. It may harm them even if it seems to you that their medical condition is similar.
This medicine is not intended for children.

1. WHAT IS THE MEDICINE INTENDED FOR:

For treatment of overactive bladder conditions, manifested by urinary urgency and frequency and/or urinary incontinence.

Therapeutic group
Muscarinic receptor antagonist

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine:
- when you are breastfeeding.
- if you have a known sensitivity to tolterodine or to any of the other ingredients of the medicine.
- if you are suffering from:
  - urinary retention (inability to pass urine).
  - obstruction or disturbances in the digestive system (e.g., ulcerative colitis, toxic megacolon).
  - uncontrolled narrow-angle glaucoma.
  - myasthenia gravis (a disease manifested by severe muscle weakness).

Special warnings regarding use of the medicine:
- Use of this medicine may cause blurred vision.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

❗ Do not use the medicine without consulting the doctor before starting treatment
- if you are pregnant or plan to become pregnant.

If you are suffering, or have suffered in the past, from:
- heart problems, arrhythmia or if you are taking antiarrhythmic medicines.
- heart diseases such as cardiomyopathy (weak heart muscle), ischemic heart disease, in which there is a disturbance in the blood supply to the heart, heart failure.
- in conditions in which there are low calcium, potassium or magnesium levels in the blood (hypocalcemia, hypokalemia, hypomagnesemia).
- hiatal hernia.
- severe constipation or reduced intestinal motility.
- if you are suffering, or have suffered in the past, from neuronal diseases (autonomic neuropathy), which affect blood pressure, the digestive system or sexual function.
- if you are suffering, or have suffered in the past, from impaired function of:
  - the eyes (e.g., glaucoma).
  - the liver.
  - the kidney (failure) or urinary system (difficulty passing urine/ weak urine flow).
  - the digestive system (digestive system disturbances such as narrowing of the pylorus or a disturbance that causes a problem in passage or digestion of food).

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

Concomitant use of tolterodine and the following medicines is not recommended:
- Antibiotics (e.g., erythromycin and clarithromycin)
- Antifungals (e.g., itraconazole, ketoconazole, miconazole)
- Medicines to treat the human immunodeficiency virus

Exercise caution when concomitantly using Tolterodine ER Teva and the following medicines:
- Medicines that affect the digestive system (cisapride, metoclopramide)
- Antiarrhythmic medicines (e.g., quinidine, amiodarone, procainamide, sotalol)
- Other muscarinic antagonists or anticholinergics (e.g., antispasmodics)

❗ Use during pregnancy
If you are planning a pregnancy or are pregnant, consult the doctor before starting treatment with the medicine.

❗ Use when breastfeeding
Do not use this medicine when breastfeeding.

❗ Driving and using machines
Use of this medicine may cause dizziness, tiredness and blurred vision, and therefore requires that caution be exercised when driving a car, operating dangerous machinery and in any activity that requires alertness.

3. HOW SHOULD YOU USE THE MEDICINE?

Dosage
Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:
One Tolterodine ER Teva 4 mg capsule per day.
The dosage will be adjusted by the doctor, especially in patients with liver problems, kidney problems or in patients suffering from side effects to the medicine.
The medicine is not intended for children.

Do not exceed the recommended dose.

Instructions for use of the medicine:
- Swallow the capsule with a glass of water before or after a meal.
- The capsules are Extended Release and should not be chewed.

If you took an overdose, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the scheduled time, do not take a double dose, rather, take the next dose at the usual time. Never take two doses together to compensate for a forgotten dose.

Adhere to the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with this medicine without first consulting the doctor or pharmacist.

How can you contribute to the success of the treatment?
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Tolterodine ER Teva may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Refer to a doctor immediately if the following occur
symptoms of angioedema (swelling of the face, lips, mouth, tongue or throat, which may cause swallowing or breathing difficulties, hives [skin rash]).
In addition, refer to a doctor if you experience an allergic reaction (symptoms include itching, rash, hives) or symptoms of heart failure such as chest pain, breathing difficulties or increased tiredness (also at rest), breathing difficulties when sleeping at night, swelling of the legs. These effects are uncommon (frequency of up to 1:100).

Additional side effects:

Very common side effect
Dry mouth.

Common side effects
Sinusitis.
Dizziness, sleepiness and headache.
Dry eyes and vision disturbances.
Digestion disturbances, abdominal pain, flatulence, constipation, diarrhea.
Pain when passing urine.
Tiredness and edema.

Uncommon side effects
Allergic reactions.
Nervousness.
Sensation of pins and needles in the fingertips and toes.
Palpitations, irregular heart rate, heart failure.
Inability to pass urine.
Chest pain.
Memory impairment.
Vertigo.

Additional side effects reported with the preparation
Severe allergic reactions.
Confusion, hallucinations, disorientation, worsened dementia in patients being treated for dementia.
Flushing of the skin, dry skin.
Vomiting and heartburn.
Tachycardia.

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects:
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
Store in a dry place, below 25°C.
Do not discard medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Tolterodine ER Teva 2 mg
Sugar Spheres (Sucrose, Corn Starch), Ethylcellulose, Hypromellose (Hydroxypropyl Methylcellulose), Triethyl Citrate, Hydroxypropyl Cellulose, D&C Yellow 10, FD&C Green 3, Titanium Dioxide, Gelatin.
Each capsule contains approximately 77.5 mg sucrose.

Tolterodine ER Teva 4 mg
Sugar Spheres (Sucrose, Corn Starch), Ethylcellulose, Hypromellose (Hydroxypropyl Methylcellulose), Triethyl Citrate, Hydroxypropyl Cellulose, Brilliant Blue FCF/FD&C Blue 1, Titanium Dioxide, Gelatin.
Each capsule contains approximately 155 mg sucrose.

What the medicine looks like and the contents of the package
Tolterodine ER Teva 2 mg:
Each package contains 30 capsules in blisters. The capsules are light green, with the numbers 93 and 7163 imprinted on them.

Tolterodine ER Teva 4 mg:
Each package contains 30 capsules in blisters. The capsules are aqua blue, with the numbers 93 and 7164 imprinted on them.

Manufacturer and license holder:
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach Tikva

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Tolterodine ER Teva 2 mg:
142.32.31790

Tolterodine ER Teva 4 mg:
142.33.31791

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