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

The medicine is dispensed with a doctor's prescription only

Solifenacin Teva® 5 mg Tablets

Composition

Each tablet contains:
Solifenacin succinate 5 mg

Solifenacin Teva® 10 mg Tablets

Composition

Each tablet contains:
Solifenacin succinate 10 mg

Inactive and allergenic ingredients in the preparation - see section 2 "Important information about some of the ingredients of the medicine" and section 6 - "Further Information".

Read the 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 it on to others. It may harm them even if it seems to you that their ailment/medical condition is similar. Do not use the medicine in children and adolescents under the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of urinary incontinence and/or conditions of increased urinary frequency and urgency in patients with an overactive bladder.

Therapeutic group: Anticholinergics

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to solifenacin or to any of the additional ingredients contained in the medicine.
- In case of urinary retention, severe disorders of the digestive system (toxic megacolon), myasthenia gravis (extreme muscle weakness), intraocular pressure, accompanied by decreased vision (glaucoma).
- In patients undergoing kidney dialysis and in patients with severe liver insufficiency.
- In patients with severe kidney disease or with moderate liver disease, who are being concomitantly treated with another medicine that reduces the clearance of solifenacin from the body, such as ketoconazole.

Special warnings regarding use of the medicine

Before beginning treatment with Solifenacin Teva, tell the doctor if:
You have a problem passing urine (partial obstruction), you are suffering from constipation, you are at risk of slowed gastrointestinal activity (gastrointestinal motility), you are suffering from an acute kidney disease, you are suffering from a moderate liver disease, you are suffering from a hiatus hernia or heartburn, you are suffering from a nervous system disturbance (autonomic neuropathy).

Children and adolescents
Solifenacin Teva is not indicated for use in children and adolescents under the age of 18.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, especially if you are taking:

- Other anticholinergic medicines – may increase the side effects of both medicines.
- Cholinergic medicines – may reduce the effect of Solifenacin Teva.
- Metoclopramide, cisapride are expected to cause the digestive system to work faster – solifenacin may delay their activity.
- Ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil, diltiazem – cause a decreased rate of solifenacin clearance from the body.
- Rifampicin, phenytoin, carbamazepine – may lead to an increase in the rate of clearance of solifenacin from the body.
- Bisphosphonates – may cause or worsen inflammation of the esophagus.

Use of the medicine and food
The medicine can be taken with or without food.

Pregnancy, breastfeeding and fertility
Consult with the doctor.
Do not use Solifenacin Teva during pregnancy, unless the doctor decides otherwise.
Do not breastfeed while using Solifenacin Teva, as the medicine may pass into the breast milk.

Driving and operating machinery
Use of this medicine may impair alertness and/or cause blurred vision and therefore caution must be exercised when driving a car, when operating dangerous machinery and when engaging in any activity that requires alertness.

Important information about some of the ingredients of the medicine
This medicine contains lactose. If you have a known intolerance to certain sugars, consult the doctor before taking the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:
One tablet of 5 or 10 mg per day. The dosage will be individually determined by the doctor.
It is recommended to take the medicine at the same time each day.
Do not exceed the recommended dose.
Swallow the medicine whole with water.
Crushing/halving/chewing: Do not halve (there is no score line); there is no information regarding chewing or crushing the tablet.
If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
Side effects of overdose: headache, dry mouth, dizziness, blurred vision, drowsiness, hallucinations, over-excitability, convulsions, breathing difficulties, accelerated heartbeat, dilated pupils, urinary retention.
If you forgot to take the medicine at the designated time, do not take a double dose. Take the next dose at the usual time and consult the doctor.
Adhere to the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor. Discontinuation of the treatment may lead to recurrence or worsening of the symptoms of an overactive bladder.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Solifenacin Teva 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.
Discontinue use and refer to a doctor if:
An allergic reaction of the skin, manifesting by edema under the skin surface and accompanied by respiratory difficulties occurs – an effect called angioedema.
Refer to a doctor immediately if:
You experience an allergic attack, or a severe skin reaction (e.g., blisters and peeling of the skin).
Very common side effect occurs in more than one user in ten:
Dry mouth.
Common side effects occurring in 1-10 in 100 users:
Constipation, blurred vision, nausea, indigestion, e.g., sensation of a full stomach, abdominal pains, burping, heartburn and stomach discomfort.
Uncommon side effects occurring in 1-10 in 1,000 users:
Urinary tract or bladder infection, drowsiness and tiredness, changes in sense of taste, dryness/irritation in the eyes, throat, skin or nose, difficulty in passing urine, heartburn, gastroesophageal reflux, edema of the lower part of the leg.
Rare side effects occurring in 1-10 in 10,000 users:
Intestinal obstruction, urinary retention, severe constipation, dizziness, headache, vomiting, itching, rash.
Very rare side effects occurring in less than one user in 10,000:
Hallucinations, confusion, allergic rash.
Side effects of unknown frequency:

- Changes in electrical conductivity of the heart (changes in ECG), irregular heart rhythm, palpitations, rapid pulse
- Decreased appetite, high potassium levels in the blood, which may cause an abnormal heart rhythm
- High intraocular pressure
- Voice disorder
- Liver dysfunction
- Muscle weakness
- Kidney dysfunction

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with 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://sideeffects.health.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 unless explicitly instructed to do so by 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 unused medicines. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Solifenacin Teva 5 mg:
Microcrystalline cellulose, lactose, crospovidone, povidone, magnesium stearate, silica colloidal anhydrous, polyvinyl alcohol, titanium dioxide, macrogol/PEG 3350, talc, iron oxide yellow.
Each tablet contains 78 mg lactose.
Solifenacin Teva 10 mg:
Microcrystalline cellulose, lactose, crospovidone, povidone, magnesium stearate, silica colloidal anhydrous, polyvinyl alcohol, titanium dioxide, macrogol/PEG 3350, talc, carmine, iron oxide yellow, iron oxide red.
Each tablet contains 78 mg lactose.
What the medicine looks like and the contents of the package:
Solifenacin Teva 5 mg: Yellowish-yellow, round, film-coated tablet. 'S5' appears on one side of the tablet and 'TEVA' on the other. Each package contains 30 tablets packed in blisters.
Solifenacin Teva 10 mg: Pinkish-pink, round, film-coated tablet. 'S10' appears on one side of the tablet and 'TEVA' on the other. Each package contains 30 tablets packed in blisters.
Name of Manufacturer and License Holder and its Address:
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva.
This leaflet was revised in December 2020.
Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Solifenacin Teva 5 mg: 150.22.33626
Solifenacin Teva 10 mg: 150.23.33620

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