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

This 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

For a list of inactive ingredients in the preparation see section 6 - "Further Information".

Read the package insert carefully in its entirety before using this 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 is similar.
This medicine is not usually intended for children and adolescents under the age of 18 years.

1. WHAT IS THIS MEDICINE INTENDED FOR?

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

Therapeutic group:
The active ingredient belongs to the group of anticholinergics (antispasmodics).

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine if:
- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine, see section 6 - "Further Information" in this leaflet.
- Do not use the medicine in patients suffering from urinary retention (cannot urinate or empty the bladder completely).
- If you suffer from severe disorders of the digestive system (including toxic megacolon, which is a complication of ulcerative colitis).
- If you suffer from a muscle disease called myasthenia gravis, which causes extreme muscle weakness.
- If you suffer from intraocular pressure, including gradual reduction in vision (glaucoma).
- Do not use in patients with severe liver disease.
- Do not use in patients with severe kidney disease or with a liver disease, who concomitantly take medicines which may inhibit the removal of Solifenacin from the body (CYP3A4 inhibitor), such as ketoconazole.
- Do not use in patients undergoing kidney dialysis.

Before treatment with Solifenacin Teva®, tell the doctor if:
- If you suffer from difficulty in emptying your bladder or difficulty urinating.
- If you are pregnant, planning pregnancy or are breastfeeding.
- If you suffer, or have suffered in the past, from impaired function of: the heart and/or blood vessels, the liver, the kidney, the urinary system or bladder obstruction.
- If you suffer from severe kidney disease or from a liver disease.
- If you suffer from impairment of the digestive system, such as intestinal obstruction, constipation, reduced motility (atonia).
- If you suffer from impairment of the nervous system (e.g., autonomic neuropathies).
- If you suffer from hiatus hernia or heartburn.
- If you take bisphosphonates.

Special warnings regarding use of the medicine
- Before using the medicine, the reasons for frequent urination, e.g., heart failure or kidney disease, must be checked. If there is a bacterial infection, the doctor will give you appropriate antibiotic treatment.
- The medicine contains lactose and may cause allergy in patients sensitive to lactose.
- Avoid situations where the body becomes overheated such as during physical activity or hot weather.
- Angioedema, an allergic reaction of the skin characterized by edemas in the deep layers of the skin and accompanied by breathing difficulties, has been reported in patients who were treated with the medicine. In case of angioedema, discontinue use of the medicine and refer immediately to a doctor.

! If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking or are planning to take:
- Medicines that affect the digestive system, e.g., cisapride and metoclopramide.
- Medicines that inhibit the CYP3A4 enzyme, e.g., ketoconazole, ritonavir, nelfinavir, itraconazole.
- Medicines that are metabolized by the CYP3A4 enzyme - verapamil, diltiazem.
- Cholinergic Medicines, e.g., pilocarpine (for glaucoma).
- Rifampicin, phenytoin, carbamazepine.
- Medicines from the bisphosphonates group.
- Other anticholinergic medicines – may increase the risk of side effects, or intensify the activity of the medicines.
- Other cholinergic medicines – may reduce the effect of Solifenacin Teva®.

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

! Pregnancy and breastfeeding
Consult with a doctor regarding use of the medicine if you are pregnant.
Do not breastfeed during the treatment as the medicine may pass to the baby in the breast milk.

! Use in children
This medicine is not usually intended for children and adolescents under the age of 18 years.

! Driving and use of machines
Use of this medicine may cause blurred vision or sometimes tiredness or sleepiness. If you experience any of these effects, do not drive or operate dangerous machines.

! Important information about some of the ingredients of the medicine
This medicine contains lactose. If you are intolerant to certain sugars, inform the doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to the doctor's instructions.
Check with the doctor or pharmacist if you are not sure.
The dosage is according to the doctor's instructions only.
Do not chew and do not crush the tablets. Swallow the medicine whole, with water.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage, unless otherwise instructed by the doctor, is:
One tablet of Solifenacin Teva® 5 or 10 mg once a day.
Do not exceed the recommended dose.
It is recommended to take the medicine each day at the same time.

If you accidentally 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.

Symptoms of overdose include: headache, dry mouth, dizziness, drowsiness, blurred vision, hallucinations, convulsions, over-excitability, breathing difficulties, elevated heart rate (tachycardia), urinary retention, dilated pupils – stop treatment and refer to a doctor immediately!

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 without consulting with the doctor or pharmacist. The symptoms from which you suffered may recur or worsen.

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 may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Refer to a doctor immediately:
- In case of an allergy attack or severe skin reaction (blisters and peeling of the skin): consult with the doctor or pharmacist immediately.
- If a severe allergy (angioedema) appears that causes swelling of the face, tongue, lips and/or throat which might cause swallowing or breathing difficulties. Stop treatment with the medicine and refer to a doctor immediately.
- Strong abdominal pain, intestinal obstruction, serious constipation, urinary retention (rare): stop treatment and refer to a doctor immediately!
- Dizziness, vomiting, headache, rash, itching, confusion, hallucinations. Stop treatment and refer to a doctor immediately!
- Changes in electrical conduction of the heart (changes in ECG), irregular heart rate. Stop treatment and refer to a doctor immediately!

Additional side effects:
Side effects occurring frequently:
- dry mouth
- blurred vision
- constipation, nausea, indigestion, abdominal pain/discomfort, heartburn, burping

Side effects occurring infrequently:
- urinary tract infection or bladder infection
- tiredness or sleepiness
- impaired sense of taste
- dry eyes, dryness of the nose, throat and skin
- difficulty in passing urine
- gastro-esophageal reflux
- edema of the lower limbs

Rare/very rare side effects:
- constipation (fecal impaction)
- urinary retention
- dizziness, headache
- vomiting
- itching, rash
- hallucinations, confusion

Side effects whose frequency is unknown:
- decreased appetite
- increase in the potassium levels in the blood (may influence heart rate)
- increase in intraocular pressure
- changes in ECG (electrical activity of the heart), irregular heart rate (Torsade de Pointes)
- voice impairment
- impairment of liver function
- muscle weakness
- impairment of kidney function

If any of the side effects occurs, worsens, or if you suffer from a side effect mentioned in the leaflet, consult the doctor.

Effects of overdose:
Headache, dry mouth, dizziness, drowsiness, blurred vision, hallucinations, over-excitability, elevated heart rate, dilated pupils, convulsions, urinary retention, breathing difficulties – stop treatment and refer to a doctor immediately!

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants 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 medicines no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Microcrystalline Cellulose, Lactose Anhydrous, Crospovidone, Povidone, Magnesium Stearate, Silica Colloidal Anhydrous, Polyvinyl Alcohol, Titanium Dioxide, Macrogol/PEG 3350, Talc, Iron Oxide Yellow, Iron Oxide Red (only in 10 mg), Carmine (only in 10 mg).

Each tablet contains 78 mg of lactose.

What does the medicine look like and what are the contents of the package:
Each package contains 30 tablets.
Solifenacin Teva® 5 mg: Yellowish, round, film-coated tablet. S5 appears on one side of the tablet and the word TEVA on the other.
Solifenacin Teva® 10 mg: Pink, round, film-coated tablet. S10 appears on one side of the tablet and the word TEVA on the other.

Manufacturer and license holder:
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach Tikva 49131.

This leaflet was checked and approved by the Ministry of Health in November 2013.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Solifenacin Teva® 5 mg: 150.22.33626.00
Solifenacin Teva® 10 mg: 150.23.33620.00

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