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

The medicine is dispensed with a doctor's prescription only

Solifenacin-Trima 5 mg, 10 mg Tablets

Solifenacin-Trima 5 mg each tablet contains:
Solifenacin succinate 5 mg
Solifenacin-Trima 10 mg each tablet contains:
Solifenacin succinate 10 mg
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 you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.
The medicine is not intended for children and adolescents under 18 years of age.

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. Before using the medicine, check the reasons for increased urinary frequency (e.g., heart or kidney problem, urinary tract infection).
Do not use if you suffer from kidney and/or liver failure and/or glaucoma.
Do not use if you have a known allergy to lactose, since the medicine contains lactose.
The medicine is not intended for children and adolescents under 18 years of age.
In some of the patients who used solifenacin succinate, angioedema was reported (an allergic skin reaction manifested by edema/swelling of the deep layers of the skin), accompanied with breathing difficulty. In the event that this effect occurs, stop treatment and contact the doctor immediately.
The medicine may cause impaired alertness and/or blurred vision and therefore, do not drive or operate dangerous machinery when using the medicine.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of urinary incontinence and/or conditions of increased urinary frequency and urgency in patients with an overactive bladder.
Therapeutic Group: Antimuscarinic

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
- you are sensitive (allergic) to the active ingredient or to any of the additional ingredients found in the medicine (e.g., lactose).
- you suffer from urinary retention, severe gastrointestinal disorders (toxic megacolon, gastric ulcer), severe muscle weakness (myasthenia gravis), glaucoma (narrow angle) or are at risk for these conditions.
- you suffer from severe liver failure.
- you suffer from severe kidney failure that requires dialysis.
- You suffer from severe kidney failure or liver failure and are **concomitantly** being treated with medicines that affect drug elimination (e.g., ketoconazole).

Special warnings regarding use of the medicine
- Before using the medicine, your doctor will check possible factors for urinary frequency (e.g., heart or kidney problem, urinary tract infection), for example: in case of bacterial infection, the doctor will consider appropriate antibiotic treatment.
- Avoid situations of excessive body temperature increase such as physical exercise or hot weather. Using the medicine under such conditions may cause heat stroke/exhaustion that is characterized by decreased sweating, increased body temperature, dizziness, fatigue, nausea.
- In some of the patients who used solifenacin succinate, angioedema was reported (an allergic skin reaction manifested by edema/swelling of the deep layers of the skin) accompanied with breathing difficulty. In the event that this effect occurs, stop treatment and contact the doctor immediately.

❗ Do not use the medicine without consulting the doctor before starting treatment:
if you have a problem passing urine (partial obstruction), if you suffer from constipation, if you are at risk for reduced activity of the digestive system (stomach and intestinal motility), if you suffer from an acute kidney disease, if you suffer from a moderate liver disease, if you suffer from hiatus hernia or heartburn, if you suffer from a disturbance of the nervous system (autonomic neuropathy).

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements, inform the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking the following medicines:
- Metoclopramide or cisapride – their efficacy may be reduced.
- Medicines that include CYP3A4 enzyme (e.g., ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil, diltiazem) - may prevent/delay degradation of solifenacin.
- Other anti-cholinergic preparations – may increase the effects of both medicines.
- Cholinergic preparations – (e.g., pilocarpine for treating glaucoma) – may reduce solifenacin efficacy.
- Bisphosphonates – may cause worsening of esophagitis.

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

❗ Pregnancy and breastfeeding
Consult with the doctor.
Do not use Solifenacin-Trima during pregnancy unless the doctor decides otherwise. Do not breastfeed during use of Solifenacin-Trima since the medicine may pass into breast milk.

❗ Driving and operating machinery
The medicine may impair alertness and/or cause blurred vision, therefore do not drive or operate dangerous machinery while using the medicine.

❗ Important information about some of the ingredients of the medicine
The medicine contains lactose. Do not use if you have a known allergy.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the manner of use.
The dosage and manner of treatment will be determined by the doctor only. The usual dosage is generally: one tablet per day. It is recommended to take the medicine at the same time every day.
Do not exceed the recommended dose.
Swallow the medicine whole with water. It is forbidden to crush/halve/chew, since the tablet is coated.

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. In case of overdose, possible side effects are: headache, dry mouth, dizziness, blurred vision, drowsiness, hallucinations, convulsions, breathing difficulty, accelerated heartbeats, urinary retention, dilated pupils.

If you forget to take this medicine at its fixed time, take the next dose at the regular time and consult the doctor. Do not take a double dose.
Adhere to the treatment regimen as recommended by the doctor.

How can you contribute to the success of the treatment?
Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting the doctor or pharmacist.

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 by the list of side effects. You may not suffer from any of them.

Stop treatment and contact the doctor immediately if the following effects occur:
Angioedema (an allergic skin reaction manifested by edema in the deep layers of the skin accompanied with breathing difficulty).

Contact the doctor immediately if the following effects occur:
Allergic reaction manifested by skin rash, itching, skin blistering, swelling of the face, tongue, neck and/or extremities, shortness of breath.

Contact the doctor if the following effects occur:
Constipation lasting more than 3 days, acute stomach pain.

Additional side effects:
- **Occurring very frequently**
  Dry mouth
- **Occurring frequently**
  Constipation, nausea, gastrointestinal effects (e.g., feeling full, abdominal pain, burping, heartburn, stomach discomfort)
  Blurred vision
- **Occurring infrequently**
  Urinary tract and/or bladder infection
  Drowsiness and tiredness
  Changes in sense of taste
  Dryness in eyes, skin and/or nose
  Difficulty in passing urine
  Reflux (return of intestinal content to the esophagus), dry throat
  Edema of the lower extremities
- **Occurring rarely**
  Severe abdominal pain, intestinal obstruction, severe constipation
  Urinary retention
  Headache and dizziness
  Vomiting
  Itching, rash
- **Occurring very rarely**
  Hallucinations, confusion
  Allergic rash
- **Side effects of unknown frequency**
  Changes in ECG, irregular heart rate, accelerated heart beats
  Decreased appetite, high blood potassium levels that may cause irregular heart rate
  Increased intraocular pressure
  Changes in liver and/or kidney function
  Muscle weakness
  Vocal cord disorder

If any of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

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 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) appearing on the package. The expiry date refers to the last day of that month.
- Do not store at a temperature over 25°C.
- Store in the original package.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose anhydrous, maize starch, hydroxypropyl methylcellulose, magnesium stearate, HPMC, titanium dioxide, polyethylene glycol, D&C yellow No. 10, FD&C red No. 3, FD&C red No. 2 aluminium lakes.
Each tablet of **Solifenacin-Trima 5 mg** contains about 61 mg of lactose.
Each tablet of **Solifenacin-Trima 10 mg** contains about 122 mg of lactose.
What does the medicine look like and what are the contents of the package?
Each package contains 30 round, light yellow tablets.
License holder: Trima, Israel Pharmaceutical Products Maabarot Ltd. Maabarot 4023000 Israel.
This leaflet was checked and approved by the Ministry of Health in July 2014.
Registration number of the medicine in the National Drug Registry of the Ministry of Health:
5 mg: 152.32.33873.00
10 mg:152.33.33869.00

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

TRIMA