PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Solifenacin-Trima 5
Solifenacin-Trima 10
Film-coated tablets

Each tablet of **Solifenacin-Trima 5** contains:
Solifenacin succinate 5 mg
Each tablet of **Solifenacin-Trima 10** contains:
Solifenacin succinate 10 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some ingredients of the medicine' and section 6 'Additional information'.
Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the 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.
Do not use in children and adolescents under the age of 18.

1. What is the 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 class: anticholinergic

2. Before using the medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains.
- In case of urinary retention, severe gastrointestinal disorders (toxic megacolon), myasthenia gravis (severe muscle weakness), or intraocular pressure accompanied by decreased vision (glaucoma).
- In kidney patients undergoing dialysis and in patients with severe liver insufficiency.
- In patients with severe kidney disease or moderate liver disease who are being treated concomitantly with another medicine that decreases the removal of **Solifenacin-Trima** from the body such as ketoconazole.

Special warnings regarding the use of the medicine:
Before starting treatment with Solifenacin-Trima, inform your doctor if:
You have a problem passing urine (partial obstruction), you suffer from constipation, you are at risk of digestive system slowing down (stomach and intestinal motility), you suffer from an acute kidney disease, you suffer from a moderate liver disease, you suffer from hiatus hernia or heartburn, you suffer from disturbances of the nervous system (autonomic neuropathy).

Children and adolescents
Solifenacin-Trima is not intended 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 food supplements, tell the doctor or the 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-Trima.**
- Metoclopramide, cisapride – medicines which cause the digestive system to work faster. **Solifenacin-Trima** may inhibit their effect.
- Ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem – which decrease the rate at which **Solifenacin-Trima** is removed from the body.
- Rifampicin, phenytoin, carbamazepine – may increase the rate at which **Solifenacin-Trima** is removed from the body.
- Bisphosphonates – may cause or worsen esophagitis.

Use of the medicine and food
This medicine may be taken with/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 breastmilk.

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

Important information about some ingredients of the medicine
The medicine contains lactose. If there is a known intolerance to certain sugars, consult with your doctor before taking this medicine.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined by the doctor only. The usual dosage is: one tablet of 5 or 10 mg per day. The dosage will be determined on an individual basis by the doctor. It is recommended to take the tablet at the same time every day.

Do not exceed the recommended dose.
The medicine should be swallowed whole with water.
Crushing/halving/chewing: The tablet should not be crushed/halved/chewed due to its coating.

If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.
Side effects of overdose: Headache, dry mouth, dizziness, blurred vision, drowsiness, hallucinations, over-excitability, convulsions, breathing difficulties, rapid heart beat, dilated pupils and urinary retention.
If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.
Follow 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 the doctor. Stopping the treatment may lead to recurrence or worsening of the symptoms of overactive bladder.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using **Solifenacin-Trima** 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.
Stop using this medicine and refer to a doctor if:
You have an allergic skin reaction which manifests as edema under the skin accompanied by respiratory distress – a reaction called angioedema.

Contact the doctor immediately if you experience the following effects:
You experience an allergy attack or a severe skin reaction (e.g., blistering and peeling of the skin).

Very common side effects - side effects that occur in more than one out of ten users:
Dry mouth

Common side effects - side effects that occur in 1-10 out of 100 users:
Constipation, blurred vision, nausea, digestive disturbances such as a feeling of abdominal fullness, abdominal pain, burping, heartburn and abdominal discomfort.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:
Urinary tract and/or bladder infection, drowsiness and fatigue, changes in sense of taste, dryness/irritation of the eyes, throat, skin or nose, difficulty urinating, heartburn, gastroesophageal reflux, edema of the lower part of the leg.

Rare side effects - side effects that occur in 1-10 out of 10,000 users:
Intestinal obstruction, severe constipation, urinary retention, dizziness, headache, vomiting, itching, rash.

Very rare side effects - side effects that occur in less than one out of 10,000 patients:
Hallucinations, confusion, allergic rash.

Side effects of unknown frequency:
- Changes in the electrical activity of the heart (changes in ECG), irregular heart rate, strong heartbeats, fast heartbeat
- Decreased appetite, high blood potassium levels that may cause irregular heart rate
- High intraocular pressure
- Voice disorder
- Liver function disorder
- Muscle weakness
- Kidney function disorder

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il
Additionally, you can also report by e-mail to: safety@trima.co.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from 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.
Storage conditions:
Store in a dry place, below 25°C.

6. Additional information

In addition to the active ingredient the medicine also contains:
Lactose anhydrous, maize starch, hydroxypropyl methylcellulose, magnesium stearate, titanium dioxide, D&C yellow No. 10 aluminum lake, polyethylene glycol, erythrosine aluminum lake, FD&C blue #2 indigo carmine aluminum lake.

What does the medicine look like and what are the contents of the package
Each package contains 30 light yellow, round, biconvex, film-coated tablets.

Name and address of the manufacturer and license holder: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in November 2022 according to Ministry of Health guidelines.

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

1122C
Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

TRIMA

P00001245 PIL-1122-04