

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

The medicine is dispensed with a doctor's prescription only

THEOTRIM 100, 200, 300 Sustained-release Tablets

Composition:

Each sustained-release tablet contains:
Theotrim 100: Theophylline anhydrous 100 mg
Theotrim 200: Theophylline anhydrous 200 mg
Theotrim 300: Theophylline anhydrous 300 mg

Inactive ingredients in the preparations – see section 6.

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.

This medicine is not usually intended for children and infants below three years of age.

1) WHAT IS THE MEDICINE INTENDED FOR?

Bronchodilator for the treatment and prevention of bronchospasm in asthma, chronic bronchitis and emphysema.

Therapeutic group: The medicine belongs to the xanthine group.

2) BEFORE USING THE MEDICINE

❑ Do not use the medicine 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") or to other medicines from the xanthine group (including caffeine, aminophylline, dyphylline, etc.).
- you are suffering from porphyria (a rare disease of the blood pigments, manifested by, among others, red pigmentation of the skin, eyes, teeth and more).
- In children - abstain from concomitant administration with cough or congestion preparations that contain ephedrine.

Before treatment with Theotrim, tell the doctor if:

- you are pregnant or breastfeeding.
- you are suffering, or have suffered in the past, from impaired function of: the heart and/or blood vessels, the eyes (e.g., glaucoma), the liver, the kidney/urinary tract, the digestive system (e.g., ulcer), the thyroid gland, from fits or convulsions, from hypertension, from viral infection (e.g., flu).
- In men - you are suffering, or have suffered in the past, from a problem with prostate gland function and/or a problem in passing urine.
- you use any other preparations from the xanthine group.
- at the moment, your body temperature is high (due to illness, for example).

- you are suffering, or have suffered in the past, from addiction to alcohol.
- you smoke.

Special warnings regarding use of this medicine

- If you are sensitive to any food or medicine, especially to eggs, coffee, tea, cola, chocolate, theophylline, aminophylline, dyphylline etc., inform the doctor before taking the medicine.
- Do not eat foods grilled over coals during the course of treatment, due to reduction of the efficacy of the medicine.
- Inform the doctor immediately if symptoms of flu, fever or diarrhea occur, so that a change in dosage will be considered.
- If you are due to undergo surgery, inform the anesthesiologist that you are using this medicine.
- If you are due to undergo vaccination for influenza, or if you recently received a vaccination for influenza, inform the doctor that you are using this medicine.

❑ 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 the following medicines:

- Medicines affecting the central nervous system (e.g., sedatives, hypnotics, medicines for Parkinson's, epilepsy, depression, lithium, anti-allergics, surgical anesthetics, narcotic analgesics).
- Anticoagulants (e.g., ticlopidine).
- Cough and cold medicines.
- Antibiotics - erythromycin, clarithromycin, clindamycin, quinolones (norfloxacin, ciprofloxacin or levofloxacin).
- Contraceptive pills.
- Medicines to lower blood pressure and for the heart (e.g., propranolol or other beta blockers, furosemide, diuretics, calcium channel blockers, adenosine, moricizine, isoprenaline, mexiletine, propafenone).
- Medicine to treat ulcer or heartburn (e.g., cimetidine, ranitidine, nizatidine).
- Allopurinol, sulfapyrazone (for gout).
- Nicotine (in preparations for cessation of smoking).
- Influenza vaccine.
- Rifampicin, isoniazid (for tuberculosis).
- Medicines to treat cancer, e.g., interferon, methotrexate, lomustine, aminoglutethimide.
- Other medicines to treat asthma or respiratory problems, e.g., other medicines from the xanthine group, salbutamol, terbutaline, salmeterol.
- Steroids.
- *Hypericum perforatum* (St. John's Wort) (an herbal medicine for the treatment of depression).
- Oxpentifylline to treat vascular diseases.
- Carbimazole (to treat the thyroid gland).
- Fluconazole (to treat fungal infection).
- Ritonavir (to treat AIDS).
- Doxapram (to speed up breathing).
- Disulfiram (to treat alcoholism).
- Thiabendazole (to treat worms).

❑ Use of the medicine and food

Do not take this medicine with tea, coffee, cola or chocolate. Take the medicine on an empty stomach (approximately one hour before meals or two hours after meals) or with a small amount of food when there are digestive system disturbances.

❑ Use of the medicine and alcohol consumption

Do not drink wines or alcoholic beverages during the course of treatment with the medicine.

❑ Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult the doctor before use.

❑ Smoking

If you smoke or use preparations containing nicotine (e.g., gum for smoking cessation) - inform the doctor before starting treatment with this medicine.

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.

The dosage and treatment regimen will be determined by the doctor only.

Use this medicine at set intervals, as determined by the attending doctor.

Do not exceed the recommended dose.

Do not halve! Do not chew! Do not crush! Swallow the medicine with a lot of water.

Tests and follow-up

During the course of treatment with this medicine, tests for theophylline level in the blood should be performed.

If you took an overdose, or if a child has 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.

Possible symptoms in case of overdose are: abdominal pains, nausea and/or vomiting, irregular or rapid heartbeats, restlessness, convulsions. Side effects occur up to 12 hours after taking an overdose.

If you forgot to take the dose and you remembered within 4 hours of the dosing time, take it as soon as you remember. Take the next dose at the regular time. If more than 4 hours from the dosing time have passed, consult a doctor; but never take two doses together or close to each other!

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

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 Theotrim 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 effects develop:

- Dizziness, recurrent vomiting, bloody vomit, nausea, tremor, seizures, dry mouth, increased or irregular heart rate, decrease in blood pressure, severe or persistent abdominal pain, changes in urination, heartburn, confusion or behavioral change, increased blood sugar levels.

- Occurrence of signs typical of a severe allergic reaction: heavy breathing, worsening of breathing difficulties, swelling of the eyelids, lips, face, sudden irritation or rash over the entire body.

Additional side effects:

Diarrhea, abdominal pains, headaches, sleep disorders, agitation, nervousness, anxiety, vomiting, restlessness, rapid heartbeats, joint pain (as a result of increased uric acid in the blood).

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 with the doctor.

Side effects and drug interactions in children and infants:

Parents must report to the attending doctor about any side effect and additional medicine being given to the child! See above for the list of special side effects and drug interactions.

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>

Side effects can also be reported via email: safety@trima.co.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 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/blister. The expiry date refers to the last day of that month.
- Store in a dry place, below 25°C.

6) FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Albumen, magnesium stearate, hydroxypropyl methylcellulose (HPMC), titanium dioxide, polyethylene glycol 400.

What does the medicine look like and what are the contents of the package?

Each pack contains 30 round, white tablets with a score line on one side.

Manufacturer and license holder: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

This leaflet was checked and approved by the Ministry of Health in: December 2015.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Theotrim 100 mg: 050.47.23896.00

Theotrim 200 mg: 050.48.23897.00

Theotrim 300 mg: 050.49.23898.00

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Maabarot 4023000
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