

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986
This medicine is dispensed with a doctor's prescription only

Montelukast-Trima 4 mg Chewable Tablets

Each chewable tablet contains montelukast 4 mg (as sodium)

Montelukast-Trima 5 mg Chewable Tablets

Each chewable tablet contains montelukast 5 mg (as sodium)

Montelukast-Trima 10 mg Tablets

Each tablet contains montelukast 10 mg (as sodium)

Inactive ingredients and allergens: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your 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 to yours.

What is the most important information I should know about the medicine?

• **Serious mental health problems have happened in people taking montelukast** or even after treatment has stopped. This can happen in people with or without a history of mental health problems. Stop taking **Montelukast-Trima** and tell your doctor right away if you or your child have any unusual changes in behavior or thinking, including any of the following symptoms:

agitation, including aggressive behavior or hostility, attention problems, bad or vivid dreams, depression, disorientation (confusion), feeling anxious, irritability, hallucinations (seeing or hearing things that are not really there), memory problems, obsessive-compulsive symptoms, restlessness, sleep walking, stuttering, suicidal thoughts and actions (including suicide), tremor, trouble sleeping, uncontrolled muscle movements.

1. What is this medicine intended for?

Montelukast-Trima is indicated for prophylaxis and treatment of chronic asthma, including prevention of daytime and nighttime symptoms, treatment of aspirin-sensitive asthmatic patients, and prevention of exercise-induced bronchoconstriction in adult and pediatric patients two years of age and older. **Montelukast-Trima** is indicated for relief of symptoms of seasonal allergic rhinitis in adults and

pediatric patients two years old and older.

Therapeutic group: a selective antagonist of the leukotriene receptor.

Montelukast-Trima acts by blocking receptors in the airway for substances known as leukotrienes, which cause bronchoconstriction and swelling of the airways. Leukotrienes also cause allergy symptoms.

What is asthma?

Asthma is a chronic lung disease. It cannot be cured – only controlled.

Characteristics of asthma include:

- Narrowed airways causing breathing to become difficult. This narrowing worsens or improves in response to various conditions.
- Inflamed airways; that is, the lining of airways become swollen.
- Sensitive airways that react to many things, such as cigarette smoke, pollen, or cold air.

Symptoms of asthma include:

Coughing, wheezing, and chest tightness. Not all people with asthma have wheezing. For some, coughing may be the only symptom of asthma. Symptoms often occur during the night or after exercise.

What is exercise-induced asthma?

Exercise-induced asthma, more accurately called exercise-induced bronchoconstriction (EIB) occurs when exercise triggers symptoms of asthma.

What is seasonal allergic rhinitis?

- Seasonal allergic rhinitis (also known as hay fever) is triggered by outdoor allergens such as airborne pollens from trees, grasses, and weeds.
- The daytime and nighttime symptoms of seasonal allergic rhinitis typically may include:
 - stuffy, runny, itchy nose
 - sneezing
 - watery, swollen, red, itchy eyes

2. Before using the medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
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Special warnings about using this medicine Before starting treatment with Montelukast-Trima, tell your doctor:

- If you are allergic to aspirin.
- If you have or have had mental health problems.

Additional warnings

- If you or your child's asthma symptoms get worse, you should contact your doctor immediately.
- This medicine is not intended for use in acute asthmatic attacks; in such cases, follow the instructions your doctor has given you for such situations. Always have with you the inhaler medicines that the doctor told you to use for acute attack.

Avoid, as far as possible, contact with factors which may cause an asthmatic attack, such as smoking, dust mites, mold, pollens, animals, changes in weather, exposure to cold air.

Children and adolescents

The medicine is not intended for children under the age of two years.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Some medicines may affect how **Montelukast-Trima** works, or **Montelukast-Trima** may affect how other medicines work.

If you have asthma and aspirin worsens asthma symptoms, continue to avoid taking aspirin or other medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) when taking **Montelukast-Trima**. Especially inform your doctor if you are taking antiasthmatic preparations such as bronchodilators and steroids for inhalation or for oral use.

Using this medicine and food

Montelukast-Trima may be taken with or without food.

Pregnancy and breastfeeding

Before taking **Montelukast-Trima**, tell your doctor if:

- you are pregnant or plan to become pregnant. Talk to your doctor if you are pregnant or plan to become pregnant, as **Montelukast-Trima** may not be right for you.
- you are breastfeeding or plan to breastfeed. It is not known if **Montelukast-Trima** passes into breast milk. Talk to your doctor about the best way to feed your baby while taking **Montelukast-Trima**.

Important information about some of this medicine's ingredients

Every tablet contains less than 1 millimole of sodium (23 mg), so that it is essentially considered 'sodium-free'.

3. How to use this medicine?

Always take **Montelukast-Trima** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure about the dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:

Adults and adolescents 15 years of age and older with asthma and/or seasonal allergic rhinitis: one 10 mg tablet daily.

Children 6 to 14 years of age with asthma and/or seasonal allergic rhinitis: one 5 mg chewable tablet daily.

Children 2 to 5 years of age with asthma and/or seasonal allergic rhinitis: one 4 mg chewable tablet daily.

Do not exceed the recommended dose.

Montelukast-Trima should be taken once daily with or without food, according to doctor's instructions.

For asthma, **Montelukast-Trima** should be taken once daily, in the evening.

For seasonal allergic rhinitis, **Montelukast-Trima** should be taken once daily according to doctor's instructions.

Always have your inhaled rescue medicine for asthma attacks with you. Do not take an additional dose of **Montelukast-Trima** within less than 24 hours of previous dose.

Montelukast-Trima chewable tablets are not intended for use in children under 2 years of age.

Directions for use:

Montelukast-Trima 10 mg tablets

Swallow the tablet with some water and without regard to meals. If necessary, the tablet may be chewed with some water.

Montelukast-Trima 4 mg and 5 mg chewable tablets

Chew the tablet with some water before swallowing, without regard to meals.

If you have accidentally taken a higher dosage

If you have taken an overdose, or if a child has accidentally swallowed some medicine, proceed immediately to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget to take this medicine at the scheduled time, do not take the missed dose as soon as you remember, and simply continue to follow your regular schedule as recommended by the doctor. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor.

Even if your or your child's health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using **Montelukast-Trima** may cause side effects in some users. Do not be alarmed by this list of side effects, you may not experience any of them.

Montelukast-Trima may cause serious side effects, including:

- **Serious mental health problems** (see "What

is the most important information I should know about the medicine?" at the beginning of this leaflet).

- **Increase in certain white blood cells (eosinophils) and possible inflamed blood vessels throughout the body (systemic vasculitis).** Rarely, this can happen in people with asthma who take **Montelukast-Trima**. This sometimes happens in people who also take a steroid medicine by mouth, that is being stopped or its dose is being lowered.

Consult your doctor right away if you get one or more of the following symptoms:

a feeling of pins and needles or numbness of arms or legs, a flu-like illness, rash, acute inflammation (pain and swelling) of the sinuses (sinusitis).

The most common side effects of Montelukast-Trima include:

- upper respiratory infection
- fever
- headache
- sore throat
- cough
- abdominal pain
- diarrhea
- earache or ear infection
- flu
- runny nose
- sinus infection

Additionally, the following side effects have been reported as well:

- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives, rash, and itching]
- dizziness, drowsiness, sleepiness, seizures
- change in your vision, swelling or redness in or around the eye
- palpitations (irregular heart beat)
- nose bleed; stuffy nose, swelling (inflammation) of the lungs
- heartburn, diarrhea, stomach pain, dyspepsia, nausea, vomiting, dental pain
- symptoms of liver problems including nausea, vomiting, fatigue, jaundice (yellowing of the skin and eyes), dark urine, flu-like symptoms, loss of appetite, and abdominal pain
- severe skin reactions (Stevens-Johnson syndrome/toxic epidermal necrolysis/ erythema multiforme) have been reported. Symptoms include blisters, rash, scaly and itchy skin; tender red lumps under the skin, most commonly on the shins (erythema nodosum), bruising

- musculoskeletal and connective tissue disorders: joint pain, muscle aches and muscle cramps
- weakness/tiredness, swelling
- increased bleeding tendency, low blood platelet count, elevated liver enzymes, elevated number of white blood cells in the urine (pyuria)
- bedwetting in children has been reported

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

Additionally, you can report by email to: safety@trima.co.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated 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, this medicine also contains:

Mannitol, microcrystalline cellulose, croscarmellose sodium, grape flavor, magnesium stearate, iron oxide red, acesulfame potassium.

What the medicine looks like and the contents of the pack

pink, round, biconvex tablets.

Every pack contains 28 tablets in blisters.

Registration holder and manufacturer: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in November 2022 according to MOH guidelines.

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

Montelukast-Trima 4 mg: 146-92-33402-00

Montelukast-Trima 5 mg: 146-93-33403-00

Montelukast-Trima 10 mg: 146-94-33396-00