

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

The medicine is dispensed with a doctor's
prescription only

Montelukast Teva 10 mg Film-coated tablets

Composition

Each tablet contains:

montelukast (as sodium) 10 mg

For information about inactive ingredients and allergens, see section 2: 'Important information about some of this medicine's ingredients' and section 6: 'Further information'.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is this medicine intended for?

- The medicine is intended for treatment of chronic asthma, including prevention of symptoms during the day and night, treatment of asthma patients who are sensitive to aspirin, and to prevent narrowing of the airways induced by physical exertion in adults and adolescents over 15 years of age.

- The medicine is intended to relieve symptoms of seasonal allergic rhinitis in adults and adolescents over 15 years of age.

Therapeutic group:

Montelukast is a selective antagonist of the leukotriene receptor. In other words, montelukast works by blocking receptors to leukotriene in the airways. Leukotrienes are chemical substances that cause narrowing and swelling of the airways. Leukotrienes also cause allergy symptoms.

What is asthma?

Asthma is a chronic lung disease; it cannot be cured, it can only be controlled.

Asthma typically includes:

- Narrowed airways which make it difficult to breathe. This narrowing of airways worsens and improves in response to various conditions.
- Inflammation of the airways, which means swelling in the lining of the airways.
- 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 who have asthma have wheezing. In some people the only symptom of asthma will be a cough. Symptoms usually appear during the night or after exercise.

What is exercise-triggered asthma?

Asthma triggered by exercise, more accurately known as exercise-induced bronchoconstriction (EIB), occurs when exercise triggers the symptoms of asthma.

What is seasonal allergic rhinitis?

- Seasonal allergic rhinitis (also known as hay fever) is triggered by external allergens such as airborne pollen from trees, grass, and weeds.
- The daytime and nighttime symptoms of seasonal allergic rhinitis usually 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.

Special warnings regarding use of the medicine

Before treatment with Montelukast Teva 10 mg, tell the doctor:

- about all your current and past medical problems or allergies, including allergy to aspirin.
- if you are sensitive to any food or medicine.
- if you are suffering, or have suffered in the past, from impaired liver function.
- if you are pregnant, planning to have a baby or are breastfeeding.

Other warnings:

- If your asthma symptoms get worse, contact your doctor immediately.
- This medicine is not intended for treatment of acute asthma attacks; in such cases, follow the instructions provided by your doctor for these situations. Be sure to always carry with you the medicine inhalers your doctor has instructed you to use during an acute attack.
- In rare cases, patients taking Montelukast experience a combination of several symptoms that do not pass or even get worse. These symptoms may include:
 - flu-like illness
 - rash
 - tingling feeling like pins and needles or numbness in the arms or legs
 - difficulty breathing
 - acute inflammation (pain and swelling) in the sinuses (sinusitis)

These symptoms usually, but not always, occurred in patients taking oral corticosteroid tablets to treat their asthma, when the dosage of the steroid medicines was slowly lowered or stopped. Although it has not been proved that montelukast causes these symptoms, tell your doctor immediately if you experience any of the symptoms listed above.

- Behavior and mood related changes have been reported in patients taking montelukast. If you experience such changes while you are taking Montelukast Teva 10 mg (see section 4: 'Side effects') tell your doctor.

Other medicines and montelukast

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. In particular, inform your doctor if you are taking: anti-asthmatic medicines such as bronchodilators, and inhaled or oral steroids.

Use of the medicine and food

Montelukast Teva 10 mg can be taken with or without food.

Pregnancy and breastfeeding

Do not use this medicine without consulting your doctor first if you are pregnant, planning to have a baby or are breastfeeding.

Use in children

This medicine is not for use in children.

Driving and use of machinery

Montelukast is not expected to affect your ability to drive or operate machines. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with montelukast may affect some patients' ability to drive or operate dangerous machinery.

Important information about some of this medicine's ingredients

Montelukast Teva 10 mg contains lactose. If your doctor has told you that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

This medicine contains less than 23 mg of sodium so it is considered sodium free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

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

The usual dosage is:

Adults and adolescents above 15 years of age to treat asthma and/or seasonal allergic rhinitis:

One 10 mg tablet, once a day.

Do not exceed the recommended dosage.

Take Montelukast Teva 10 mg once a day with or without food, as instructed by your doctor.

To treat asthma, take Montelukast Teva 10 mg once a day, in the evening.

To treat seasonal allergic rhinitis, take Montelukast Teva 10 mg once a day, as

instructed by your doctor.

Make sure that your inhalers for use during an acute attack of asthma are always within reach. Do not take an additional dose of Montelukast Teva 10 mg within 24 hours from the previous dose.

How to take Montelukast Teva 10 mg:

Do not chew! Swallow the tablet with some water, regardless of meals.

Do not halve the tablet (there is no score line).

If you take more Montelukast Teva 10 mg than you should

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

Do not induce vomiting without an explicit instruction from the doctor!

If you forget to take Montelukast Teva 10 mg

If you forgot to take the medicine at the required time, do not take the missed dose when you remember it. Resume the usual schedule for taking the medicine instructed by your doctor. Do not take a double dose to make up for the forgotten dose.

How can you contribute to the success of your treatment?

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health or you experience an asthma attack, do not stop treatment or change the times you take it without consulting your doctor.

As far as possible, avoid contact with triggers that can start an asthma attack such as smoking, dust mite, mold, pollen, animals, changes in weather, exposure to cold air.

If you have asthma and aspirin makes your asthma symptoms worse, continue avoiding aspirin or other medicines known as nonsteroidal anti-inflammatory drugs (NSAIDs) while you are taking Montelukast Teva 10 mg.

Do not take medicines in the dark! Check the label and dose every time you take the 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 Montelukast Teva 10 mg may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

See your doctor immediately if you experience any of the following side effects while using Montelukast Teva 10 mg:

- Behavior and mood related changes [agitation including aggressive behavior or hostility, depression, disorientation (confusion), attention disorders, bad or vivid dreams, feeling anxious, hallucinations (seeing or hearing things that are not there), insomnia, irritability, impaired memory, restlessness, sleep-walking, suicidal thoughts and actions (including suicide), tremor].

- Increase in certain white blood cells (eosinophils), inflammation of blood vessels throughout the body (multiple organ vasculitis) is possible. Symptoms of these conditions may include: flu-like illness, rash, tingling feeling like pins and needles or numbness in the arms or legs, severe inflammation (pain and swelling) in the sinuses (sinusitis). These symptoms may rarely occur in people with asthma who take Montelukast Teva 10 mg or in people who are also taking oral steroids, when the dosage of the steroid medicines is slowly lowered or stopped.

Montelukast is usually well tolerated. The most common side effects reported in studies were:

- upper respiratory infection
- fever

- headache

- throat ache

- cough

- stomach ache

- diarrhea

- ear ache or ear infection

- flu

- runny nose

- sinus infection

In addition, the following side effects have also been reported:

- increased tendency to bleed, low platelet count

- allergic reactions [including swelling of the face, lips, tongue and/or throat (which may cause difficulty breathing or swallowing), hives, rash, and itching]

- dizziness, drowsiness, pins and needles sensation/numbness, seizures

- palpitations

- nosebleed, stuffy nose, swelling (inflammation) of the lungs

- heartburn, diarrhea, indigestion, nausea, vomiting

- inflammation of the liver

- bruising, rash, severe skin reactions (erythema multiforme) which may appear suddenly

- joint pain, muscle pain, and muscle cramps

- weakness/tiredness

- swelling

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.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

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 and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

- Do not use this 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 and dark place, below 25°C.

6. FURTHER INFORMATION

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

Lactose monohydrate, pregelatinized starch, sodium starch glycolate, hydroxypropyl cellulose, sodium laurylsulfate, hypromellose, titanium dioxide, magnesium stearate, iron oxide yellow, iron oxide red.

What the medicine looks like and contents of the package:

Beige, round, film-coated tablet debossed with '93' on one side and '7426' on the other side.

Each package contains 28 or 30 tablets. Not all pack sizes may be marketed.

Registration holder name and address

Abic Marketing Ltd., POB 8077, Netanya.

Manufacturer name and address

Teva Operations Poland Sp. zo.o, Warsaw, Poland.

This leaflet was reviewed and approved by the Ministry of Health in November 2014 and revised in December 2018 in accordance with Ministry of Health guidelines.

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

140.54.31552