

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

The medicine is dispensed with a doctor's prescription only

Montair 4 mg chewable tablets

Montair 5 mg chewable tablets

Each Montair 4 mg tablet contains:

Montelukast (as sodium) 4 mg

Each Montair 5 mg tablet contains:

Montelukast (as sodium) 5 mg

For a list of inactive ingredients and allergens in the preparation – see section 2 "Important information regarding some of the ingredients of the medicine" and section 6 "Additional information".

Read the entire leaflet carefully before using the medicine.

- This leaflet contains concise information about Montair. If you have other questions, ask the doctor or pharmacist.
- This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems that their medical condition is similar to yours.

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

- Severe mental health problems have been reported in people taking Montair** or even after stopping the treatment. This can happen in people with or without a history of mental health problems. Stop taking Montair and immediately tell your doctor if you or your child are experiencing unusual changes in behavior or thinking, including any of the following symptoms:

Agitation, including aggressive behavior or hostility, attention disorders, bad or vivid dreams, depression, disorientation (confusion), feeling of anxiety, irritability, hallucinations (seeing or hearing non-existing things), memory impairment, obsessive-compulsive symptoms, restlessness, sleep-walking, stuttering, suicidal thoughts and actions (including suicide), tremor, insomnia, uncontrolled muscle movements.

1. What is the medicine intended for?

Montair 4 mg

Montair 4 mg is indicated for the prevention and chronic treatment of asthma, including prevention of daytime and nighttime symptoms, treatment of aspirin-sensitive asthmatic patients and prevention of exercise-induced bronchoconstriction in adult

patients and in children two years of age and older. Montair is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and children over two years of age.

Using Montair for seasonal rhinitis is limited for patients with intolerance to alternative treatments, since the benefits of Montair may not outweigh the risk of severe mental problems (see "What is the most important information I should know about Montair?").

Montair 5 mg

Montair 5 mg is indicated for the prevention and chronic treatment of asthma, including prevention of daytime and nighttime symptoms, treatment of aspirin-sensitive asthmatic patients and prevention of exercise-induced bronchoconstriction in adult patients and in children 6 years of age and older. Montair is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and children over 6 years of age.

Using Montair for seasonal rhinitis is limited for patients with intolerance to alternative treatments, since the benefits of Montair may not outweigh the risk of severe mental problems (see "What is the most important information I should know about Montair?").

Therapeutic class: Montair is a selective leukotriene receptor antagonist. Montair acts by blocking receptors in the airways for substances called 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.

Asthma characteristics include:

- Narrowing of the airways which makes breathing difficult. This narrowing worsens and improves in response to several conditions.
- Inflamed airways; i.e. the walls of the airways become swollen.
- Sensitive airways which react to many things, such as cigarette smoke, pollen or cold air.

Asthma symptoms include:

Coughing, wheezing and chest pressure. Not all people with asthma have wheezing. For some, cough may be the only symptom of asthma. The symptoms usually occur during the night or following exercise.

What is exercise-induced asthma?

Exercise-induced asthma, more accurately called exercise-induced bronchoconstriction (EIB), occurs

when exercise induces symptoms of asthma.

What is seasonal allergic rhinitis?

- Seasonal allergic rhinitis (also called hay fever) is induced by external allergens such as airborne pollen from trees, lawns and weeds.
- The day and night symptoms of seasonal allergic rhinitis will often include:
 - Congested, 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 any of the additional components the medicine contains.

Special warnings regarding the use of the medicine

Before using Montair, inform the doctor:

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

Additional warnings:

- If your or your child's asthma symptoms worsen, contact your doctor immediately.
- The preparation is not intended for treatment of acute asthma attacks; in such cases, follow your doctor's instructions for these situations. Be sure to always carry with you the medical inhalers your doctor instructed you to use during an acute attack.

Children and adolescents

The safety and efficacy in children with asthma under 12 months of age have not been established.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, you should inform the doctor or pharmacist.

Certain medicines may affect the way Montair works, or Montair may affect the way your other medicines work.

If you have asthma and aspirin worsens your asthma symptoms, continue to avoid taking aspirin or other medicines called non-steroidal anti-inflammatory drugs (NSAIDs) while taking Montair.

Inform your doctor in particular if you are taking: preparations for asthma, such as bronchodilators and inhaled or oral steroids.

Use of the medicine and food

Montair may be taken with or without food.

Pregnancy, breastfeeding and fertility

Before taking Montair, tell your doctor if:

- You are pregnant or planning to become pregnant. Talk to your doctor if you are pregnant or planning to become pregnant, as Montair may not suit you.
- You are breastfeeding or planning to breastfeed. It is unknown whether Montair passes into your breastmilk. Talk to your doctor regarding the best way to feed your baby while taking Montair.

Important information regarding some of the ingredients of the medicine

This medicine contains less than 23 mg of sodium per tablet, and is therefore considered sodium-free.

3. How should you use the medicine?

Montair should be taken according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and the method of treatment.

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

The generally accepted dosage is:

Adults and adolescents over 15 years old, for treatment of asthma and/or seasonal allergic rhinitis: two Montair 5 mg chewable tablets once per day.

Children 6-14 years old, for treatment of asthma and/or seasonal allergic rhinitis: one Montair 5 mg chewable tablet once per day.

Children 2-5 years old, for treatment of asthma or seasonal allergic rhinitis: one Montair 4 mg chewable tablet once per day.

Do not exceed the recommended dose.

Take Montair once per day, with or without food, according to the doctor's instructions.

For treatment of asthma, take Montair once per day, in the evening.

For treatment of seasonal allergic rhinitis, take Montair once per day, according to the doctor's instructions.

Always keep your inhaled medications intended for an acute asthma attack at hand.

Do not take another dose of Montair within less than 24 hours from the previous dose. Montair chewable tablets is not intended for babies and children under two years of age.

Method of use

Chew the tablet before swallowing, regardless of meals.

If you accidentally took a high dosage of Montair

If you have taken an overdose or if a child

has accidentally swallowed this medicine, go immediately to a hospital emergency room and take the package of the medicine with you.

If you forgot to take Montair

If you forgot to take this medicine at the appointed time, do not take the forgotten dose. Continue the regular dosing schedule as you were instructed by the treating doctor. Do not take a double dose in order to compensate for a forgotten dose. Follow the treatment as recommended by the doctor.

Even if your health condition or your child's health condition improves, or if you or your child are having an asthma attack, do not stop using the medicine or change the time you are taking it without consulting the doctor.

You should avoid, if possible, coming into contact with agents that may induce an asthma attack, such as smoking, dust mite, mold, pollen, animals, weather changes, exposure to cold air. If you have asthma and aspirin worsens your asthma symptoms, continue to avoid taking aspirin or other medicines called non-steroidal anti-inflammatory drugs (NSAIDs) while taking Montair.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have any further questions about using the medicine, ask your doctor or pharmacist.

4. Side effects

As with all medicines, Montair 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.

Montair may cause severe side effects, including:

- Severe mental health problems** (see "What is the most important information I should know about Montair?" at the beginning of this leaflet).
- A rise in certain white blood cells (eosinophils) and a possible blood vessel inflammation in the entire body (systemic vasculitis).** In rare cases, these effects may occur in people suffering from asthma who are taking Montair. These effects sometimes occur in people who are also taking oral steroid medicine, when this medicine is discontinued or when its dose is reduced. **Consult your doctor immediately if you develop one or more of the following symptoms:** Sensation of pins and needles, or numbness in

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

The most common side effects of Montair include:

- Upper respiratory tract infection
- Fever
- Headache
- Sore throat
- Cough
- Abdominal pain
- Diarrhea
- Ear pain or infection
- Influenza
- Rhinitis
- Sinus infection

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

- Allergic reactions (including swelling of the face, lips, tongue and/or throat [which may cause difficulty in breathing or swallowing]), hives, rash and itching)
- Dizziness, drowsiness, somnolence, convulsions
- Changes in vision, swelling or redness inside the eye or around it
- Palpitations (irregular heart rate)
- Nose bleeding; nasal congestion, swelling (inflammation) of the lungs
- Heartburn, diarrhea, abdominal pain, digestive difficulties, nausea, vomiting, toothache
- Symptoms of liver problems, including nausea, vomiting, tiredness, jaundice (yellowing of the skin and eyes), dark urine, flu-like symptoms, loss of appetite and abdominal pain
- Severe skin reactions have been reported (Stevens-Johnson syndrome/toxic epidermal necrolysis/erythema multiforme), the symptoms include blisters, rash, scaly and itchy skin; tender red lumps under the skin, usually on the shins (erythema nodosum), bruising
- Musculoskeletal and connective tissue disorders: joint pain, muscle pain and muscle cramps
- Weakness/fatigue, swelling
- Increased tendency of bleeding, low blood platelet count, increased liver enzymes, increased number of white blood cells in the urine (pyuria)

Bedwetting in children has been reported **if a side effect occurs, if one of the side effects worsens, or if you observe any side effect not mentioned in this leaflet, consult your doctor.**

Reporting side effects

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 via the following link: <https://sideeffects.health.gov.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 of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor! Do not use Montair after the expiry date (exp. date) that appears on the package. This date refers to the last day of that month.

Storage conditions: store below 25°C.

6. Additional information

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

Mannitol, Microcrystalline Cellulose, Magnesium Stearate, Tutti Frutti Flavour, Sucralose, Disodium Edetate, FD&C Red No. 40 Lake, FD&C Blue No. 1 Lake.

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

Montair 4 mg chewable tablets are round, flat, light pink tablets.

Montair 5 mg chewable tablets are round, flat, dark pink tablets.

Package size: 7, 10, 30, 60 or 100 chewable tablets in a package.

Not all package sizes may be marketed. **Manufacturer/marketing authorization holder and address:** CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.

This leaflet was revised in 02/2025 in accordance with the Ministry of Health guidelines.

Registration numbers of the medicine in the national drug registry of the Ministry of Health:

Montair 4 mg: 145-58-31866

Montair 5 mg: 145-59-31867