

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 4 mg (as sodium)

Each **Montair** 5 mg tablet contains:

Montelukast 5 mg (as sodium)

For a list of inactive ingredients and allergens in the preparation – see section 2 "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 **Montair**. If you have other questions, ask your 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 to you that their medical condition is similar.

1. What is Montair and what is it used for?

What is Montair?

Therapeutic class: **Montair** is a selective leukotriene receptor antagonist.

Montair acts by blocking receptors in the airways for substances called leukotrienes, which cause narrowing and swelling of the airways. Leukotrienes also cause allergic symptoms.

What is Montair used for?

Montair is indicated for the treatment of chronic asthma, including prevention of daytime and nighttime symptoms, treatment of aspirin-sensitive asthmatic patients and prevention of exercise-induced bronchoconstriction in adults and pediatric patients 2 years of age and older.

Montair is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older.

What is asthma?

Asthma is a chronic lung disease. It is incurable but controllable.

Asthma characteristics include:

- Narrowed airways which make 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 pain. Not all asthma patients wheeze. 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

bronchoconstriction (EIB), occurs when exercise induces asthma symptoms.

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 taking Montair

Do not use the medicine if:

You are sensitive (allergic) to the active ingredient or any of the additional components the medicine contains.
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Special warnings regarding the use of the medicine

Before using Montair inform the doctor:

- About all medical or allergic conditions you or your child have now or used to have, including aspirin allergy.
- If you are sensitive to any type of food or medicine.
- If you suffer or suffered in the past from liver impairment.
- If you are pregnant, planning to become pregnant or breastfeeding.

Additional warnings:

- If you or your child's asthma symptoms worsen, you should contact your doctor immediately.
- The medicine is not intended for treatment of acute asthma attacks; in these cases, follow your doctor's orders for these conditions. Be sure to always carry with you the medicine inhalers your doctor ordered you to use during an acute attack.
- In rare cases, patients taking **Montair** may experience a condition where a number of symptoms do not subside or even worsen. These symptoms may include:
 - A flu-like illness
 - Rash
 - Sensation of pins and needles, or numbness in the arms or legs
 - Breathing difficulties
 - Acute (pain and swelling) sinusitis

These symptoms have usually, but not always, occurred in patients that took oral corticosteroids tablets for treatment of asthma, when their dosage was slowly reduced or stopped. Even though it was not proven that **Montair** causes this condition, you should inform the doctor right away if you develop one or more of the abovementioned symptoms.

- Mood and behavior changes were reported in patients taking **Montair**. If you or your child experience this kind of

changes while taking **Montair** (see section 4 "possible side effects"), tell your doctor about this.

Taking other medicines

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, or if you have just finished treatment with another medicine, you should inform your doctor or the pharmacist in order to prevent risks or ineffectiveness due to drug interactions.

In particular, inform your doctor if you are taking: anti-asthma medicines, 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

Do not use this medicine without consulting a doctor before starting the treatment: if you are pregnant, planning to become pregnant, or breastfeeding.

Use in children

Safety and efficacy of **Montair** in children under 12 months old have not been established.

Studies have shown that **Montair** does not affect growth rate in children.

Driving and operating machinery

Montair is not expected to affect your ability to drive a car or operate machinery. However, different people react differently to medicines. Certain side effects (such as dizziness and drowsiness) that were very rarely reported following use of **Montair**, may affect certain people's ability to drive and operate dangerous machinery.

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 to use Montair?

Always take **Montair** exactly as the doctor told you to. Check with the doctor or pharmacist if you are uncertain.

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: take two **Montair** 5 mg tablets once per day.

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

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

Do not exceed the recommended dose.
Montair should be taken once per day, with or without food,

according to the doctor's orders.

For treatment of asthma, **Montair** should be taken once per day, in the evening.

For treatment of seasonal allergic rhinitis, **Montair** should be taken once per day, according to the doctor's orders.

Always keep your inhaled medicines intended for acute asthma attack nearby. Do not take another dose of **Montair** within less than 24 hours from the previous dose.

Montair chewable tablets are not intended for babies and children under 2 years old.

Method of use:

The tablet should be chewed before swallowing, regardless of meals.

If you have taken more Montair than you should have
If you took an overdose or by mistake a child swallowed this medicine, go immediately to the emergency room of the hospital and take the package of the medicine with you. Do not induce vomiting without an explicit instruction from the doctor!

If you forgot to take Montair

If you forgot to take this medicine at the appointed time, do not take the forgotten dose as soon as you remember. You should continue with the regular dosing schedule as you were directed by the doctor. Do not take a double dose in order to compensate for a forgotten dose.

How can you contribute to the success of the treatment?
You should complete the treatment entirely, as recommended by the doctor.

Even if your condition or your child's 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.

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.

You should avoid as much as possible coming into contact with agents that may induce an asthma attack, such as smoking, dust mite, mould, 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**. If you have further questions about using the medicine, ask your doctor or pharmacist.

4. Possible side effects

As with all other 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.

You should contact the doctor immediately if you or your child experience the following side effects while using Montair:

- Changes related to behavior and mood [agitation, including aggressiveness or hostility, depression, disorientation, attention deficits, bad or perceptible dreams, feeling of anxiety, hallucinations (seeing or hearing things that do not exist), insomnia, irritability, memory impairment, restlessness, sleep-walking, suicidal thoughts and actions (including suicide), tremor].
- A rise in certain white blood cells (eosinophils) and a possible blood vessels inflammation in the entire body (systemic vasculitis). Symptoms of these conditions may include: flu-like illness, rash, sensation of pins and needles or numbness in the arms or legs and an acute inflammation (pain and swelling) of the sinuses (sinusitis). These side effects may rarely occur in people suffering from asthma who are taking **Montair** or in people taking oral steroids in addition, during steroid dosage reduction or after stopping them.

Montair is usually well tolerated. In studies, the most frequent side effects reported were:

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

In addition, the following side effects were also reported:

- An increased tendency for bleeding, low blood platelets count
- Allergic reactions [including swelling of the face, lips, tongue and/or throat (which may cause difficulties in breathing or swallowing), urticaria, rash and itching]
- Dizziness, sleepiness, sensation of pins and needles/numbness, convulsions
- Palpitations
- Nosebleed, stuffy nose, swelling (inflammation) of the lungs
- Heartburn, diarrhea, indigestion, nausea, vomiting
- Hepatitis
- Bruises, rash, severe skin reactions (Erythema Multiforme) which may occur unexpectedly
- Joint pain, muscle pain and muscle cramps
- Bedwetting in children
- Weakness/fatigue
- Swelling

If a side effect occurs, or if one of the side effects worsens, or if you observe any side effect not mentioned in this leaflet, you should consult a doctor.

Side effects and drug interactions in children and babies:

The parents should report to the doctor about every side effect and every other medicine the child is taking.

See above details about special side effects and drug interactions. 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>

5. How to store Montair?

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) that appears on the package. The expiry date refers to the last day of the month shown.

Storage conditions: Store below 25°C.

Different medicines should not be stored in the same package.

6. Additional information

What does Montair contain?

The active ingredient is montelukast, the other ingredients are: 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 Montair look like and the content 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, 100 chewable tablets in a package. Not all package sizes may be marketed.

Marketing authorization holder and address: CTS Chemical Industries Ltd., Kiryat Malachi.

The leaflet was revised in 03/2022 in accordance with the Ministry of Health guidelines.

Registration number 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

