



Patient information leaflet

(For All Products not subject to Medical Prescription)

MONAST 10 (Montelukast Sodium Tablets 10 mg)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please 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 their symptoms are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What Montelukast Sodium Tablets 10 mg is and what it is used for
2. What you need to know before you take Montelukast Sodium Tablets 10 mg
3. How to take Montelukast Sodium Tablets 10 mg
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1. What Montelukast Sodium Tablets 10 mg is and what it is used for

What is Montelukast Sodium Tablets 10 mg is

Montelukast Sodium Tablets 10 mg is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Montelukast Sodium Tablets 10 mg works

Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, Montelukast Sodium Tablets 10 mg improves asthma symptoms, helps



control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

When Montelukast Sodium Tablets 10 mg should be used

Your doctor has prescribed Montelukast Sodium Tablets 10 mg to treat asthma, preventing your asthma symptoms during the day and night.

- Montelukast Sodium Tablets 10 mg is used for the treatment of adults and adolescents 15 years of age and older who are not adequately controlled on their medication and need additional therapy.
- Montelukast Sodium Tablets 10 mg also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Montelukast Sodium Tablets 10 mg is indicated in asthma, Montelukast Sodium Tablets 10 mg can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Montelukast Sodium Tablets 10 mg should be used depending on the symptoms and severity of your asthma.

What is asthma?

Asthma is a long-term disease.

Asthma includes:

- difficulty breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions.
- sensitive airways that react to many things, such as cigarette smoke, pollen, cold air, or exercise.
- swelling (inflammation) in the lining of airways.

Symptoms of asthma include: Coughing, wheezing, and chest tightness.

What are seasonal allergies?

Seasonal allergies (also known as hay fever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds. The symptoms of seasonal allergies typically may include: stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes

**2. What you need to know before you take Montelukast Sodium Tablets 10 mg**

Tell your doctor about any medical problems or allergies you have now or have had.

Do not take Montelukast Sodium Tablets 10 mg

- if you are allergic to montelukast or any of the other ingredients of this medicine

Warnings and precautions

Talk to your doctor or pharmacist before taking Montelukast Sodium Tablets 10 mg.

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast Sodium Tablets 10 mg is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you or your child take all asthma medications prescribed by your doctor. Montelukast Sodium Tablets 10 mg should not be substituted for other asthma medications your doctor has prescribed for you.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as a flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor. You should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse

Patients should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported in adults, adolescents and children with take Montelukast Sodium Tablets 10 mg. If you develop such symptoms while taking take Montelukast Sodium Tablets 10 mg, you should consult your doctor.

Children and adolescents

Do not give this medicine to children less than 15 years of age.

There are different form(s) of this medicine available for paediatric patients under 18 years of age based on age range.

**Other medicines and Montelukast Sodium Tablets 10 mg**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines including those obtained without a prescription.

Some medicines may affect how Montelukast Sodium Tablets 10 mg works, or Montelukast Sodium Tablets 10 mg may affect how other medicines work..

Tell your doctor if you are taking the following medicines before starting Montelukast Sodium Tablets 10 mg:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)
- gemfibrozil (used for treatment of high lipid levels in plasma)

Montelukast Sodium Tablets 10 mg with food and drink

Montelukast Sodium Tablets 10 mg 10 mg film-coated tablet may be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Montelukast Sodium Tablets 10 mg.

Pregnancy

Your doctor will assess whether you can take Montelukast Sodium Tablets 10 mg during this time.

Breast-feeding

It is not known if Montelukast Sodium Tablets 10 mg appears in breast milk. You should consult your doctor before taking Montelukast Sodium Tablets 10 mg if you are breast-feeding or intend to breast-feed.

Driving and using machines

Montelukast Sodium Tablets 10 mg is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as



dizziness and drowsiness) that have been reported with Montelukast Sodium Tablets 10 mg may affect some patients' ability to drive or operate machinery.

Montelukast Sodium Tablets 10 mg film-coated tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Montelukast Sodium Tablets 10 mg

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- You should take only one tablet of Montelukast Sodium Tablets 10 mg once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.

For adults and adolescents 15 years of age and older:

The recommended dose is one 10 mg tablet to be taken daily in the evening.

If you are taking Montelukast Sodium Tablets 10 mg, be sure that you do not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.

You can take Montelukast Sodium Tablets 10 mg with or without food.

If you take more Montelukast Sodium Tablets 10 mg than you should

Contact your doctor immediately for advice.

There were no side effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

**If you forget to take Montelukast Sodium Tablets 10 mg**

Try to take Montelukast Sodium Tablets 10 mg as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet once daily.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Montelukast Sodium Tablets 10 mg

Montelukast Sodium Tablets 10 mg can treat your asthma only if you continue to take it.

It is important to continue taking Montelukast Sodium Tablets 10 mg for as long as your doctor prescribes. It will help control your asthma.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In clinical studies with Montelukast Sodium Tablets 10 mg 10 mg film-coated tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Montelukast Sodium Tablets 10 mg were:

- abdominal pain
- headache

These were usually mild and occurred at a greater frequency in patients treated with Montelukast Sodium Tablets 10 mg than placebo (a pill containing no medication).

Serious side effects

Talk with your doctor immediately if you notice any of the following side effects, which may be serious, and for which you may need urgent medical treatment.

Uncommon: the following may affect up to 1 in 100 people

- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression
- seizure



Rare: the following may affect up to 1 in 1,000 people

- increased bleeding tendency
- tremor
- palpitations

Very rare: the following may affect up to 1 in 10,000 people

- combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome) (see Section 2)
- low blood platelet count
- behaviour and mood related changes: hallucinations, disorientation, suicidal thoughts and actions
- swelling (inflammation) of the lungs
- severe skin reactions (erythema multiforme) that may occur without warning
- inflammation of the liver (hepatitis)

Other side effects while the medicine has been on the market

Very common: the following may affect more than 1 in 10 people

- upper respiratory infection

Common: the following may affect up to 1 in 10 people

- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes

Uncommon: the following may affect up to 1 in 100 people

- behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness
- dizziness, drowsiness, pins and needles/numbness
- nosebleed



- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- bedwetting in children
- weakness/tiredness, feeling unwell, swelling

Rare: the following may affect up to 1 in 1,000 people

- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

Very rare: the following may affect up to 1 in 10,000 people

- tender red lumps under the skin, most commonly on your shins (erythema nodosum)
- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland:

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Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

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Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store Montelukast Sodium Tablets 10 mg

Store below 30°C and protect from moisture.



6. Contents of the pack and other information

What Montelukast Sodium Tablets 10 mg contains

The active substance is Montelukast sodium.

Each film Coated Tablets Contains Montelukast Sodium 10 mg

The other ingredients

Lactose monohydrate Ph.Eur, Mannitol Ph.Eur, Croscarmellose sodium Ph.Eur, Hydroxypropyl cellulose Ph.Eur, Cellulose Microcrystalline Ph.Eur, magnesium stearate Ph.Eur, purified water.

What MONAST 10 (Montelukast Sodium Tablets 10 mg) looks like and contents of the pack

Beige, rounded square shaped film coated tablets debossed with “T” on one side and ‘114’ on the other side.

MONAST 10 (Montelukast Sodium Tablets 10 mg) are available in:

Container pack: 10’s Blister Pack

Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder:

Name: Hetero Labs Limited

Business Address: 7-2-A2, Hetero Corporate,
Industrial Estates,
Sanath Nagar,
Hyderabad-500 018
Telangana.

Country: INDIA

Manufacturer:

(Company) Name : M/s. Hetero Labs Limited, Unit-I
Address Village : Kalyanpur, Chakkan Road,
Tehsil : Baddi, Distt.: Solan,
Himachal Pradesh -173 205, INDIA
Telangana.

MONAST 10 (Montelukast Sodium Tablets 10 mg)



Module 1-Administrative Information And Product Information

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