

MONTAS 10

Montelukast Sodium (film coated 10mg)

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What MONTAS 10 is used for
MONTAS 10 (montelukast sodium) is used to treat:

- Asthma, including preventing your asthma symptoms during the day and night. MONTAS 10 also prevents the narrowing of airways triggered by exercise.
- Allergic rhinitis (seasonal and perennial), including daytime and nighttime symptoms: nasal congestion, runny nose, nasal itching, and sneezing; nasal congestion upon awakening, difficulty going to sleep, and nighttime awakenings; tearing, itchy, red, and puffy eyes.

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 and 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 wheeze. 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.

How do I know if I have asthma?

Your doctor will determine if you have asthma based on your symptoms and/or on how well you are able to move air out of your lungs. Your doctor may use a device called a peak flow meter or a spirometer to test your lung function.

Treatment can control asthma. It is important to treat even mild symptoms of asthma so that you can prevent them from getting worse.

How should asthma be treated?

To help prevent asthma symptoms and improve your breathing you will have to work closely with your doctor to:

Plan ways to avoid or reduce contact with conditions that may trigger an asthma episode (for example, smoking including second-hand smoke, house dust mites, cockroaches, molds, pollen, animal dander, changes in weather and temperature, and infections in the upper airway (such as colds)). Develop a treatment plan that best controls your asthma.

Why is compliance (taking my medicine as prescribed) important?

Taking your medicine as your doctor or health care provider instructs may help reduce the severity of your asthma and the frequency of your asthma attacks.

What is allergic rhinitis?

- Seasonal allergic rhinitis (also known as hay fever) is triggered by outdoor allergens such as airborne pollens from trees, grasses, and weeds.

- Perennial allergic rhinitis may occur year-round and is generally triggered by indoor allergens such as dust mites, animal dander, and/or mold spores.

- The daytime and nighttime symptoms of allergic rhinitis typically may include:

- stuffy, runny, itchy nose
- sneezing
- watery, swollen, red, itchy eyes

How MONTAS 10 works

MONTAS 10 is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and perennial, also known as outdoor and indoor nasal allergies).

Before you use MONTAS 10

When you must not take it

Do not take MONTAS 10 if you or your child

- are allergic to any of its components.

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking MONTAS 10.

Use in breast-feeding

It is not known if MONTAS 10 appears in breast milk. You should consult your doctor before taking

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MONTAS 10 if you are breast-feeding or intend to breast-feed.

Taking other medicines

In general, MONTAS 10 does not interfere with other medicines that you or your child may be taking. However, some medicines may affect how MONTAS 10 works, or MONTAS 10 may affect how your other medicines work. It is important to tell your doctor about all medicines that you or your child is using or plan to use, including those obtained without a prescription.

Can I drive or operate machinery while using Montas 10?

MONTAS 10 is not expected to affect your ability to drive a car or operate machinery.

How to use MONTAS 10

Take *MONTAS 10* once a day with or without food, as your doctor has prescribed.

- The dose for adults and adolescents 15 years and older for the treatment of asthma and/or allergic rhinitis is one 10-mg tablet daily.

For patients with asthma, take *MONTAS 10* once a day in the evening.

For patients with allergic rhinitis, take *MONTAS 10* once a day as prescribed by your doctor.

It is important to continue taking *MONTAS 10* for as long as your doctor prescribes it in order to maintain control of your or your child's asthma.

MONTAS 10 can treat your or your child's asthma only if you or your child continues to take it.

If you forget to use it

Try to take MONTAS 10 as prescribed. However, if you or your child misses a dose, just resume the

usual schedule of one tablet once daily.

If you use too much (overdose)

Contact your doctor immediately.

While you are using MONTAS 10

Things you must do

It is important that you or your child continue taking MONTAS 10 daily as prescribed by your doctor, even when you or your child has no symptoms or if you or your child has an asthma attack.

If you or your child's asthma symptoms get worse, you should contact your doctor immediately.

MONTAS 10 is not for the treatment of acute asthma attacks. If an attack occurs, you or your child should follow the instructions your doctor has given you for that situation.

Behavior and mood-related changes have been reported in patients taking MONTAS 10. If you or your child experience these changes while taking MONTAS 10 (see "**Side effects**"), tell your doctor.

Things you must not do

If you have been prescribed the 10 mg tablets, do not take two 5 mg chewable tablets in its place. If you have been prescribed the 5 mg chewable tablets, do not take half a 10 mg tablet in its place.

The different strength tablets may not have the same effect, as they are absorbed slightly differently in the body.

Do not take MONTAS 10 to relieve an acute asthma attack. In case of an acute asthma attack, follow your doctor's instructions on what reliever medicine to use.

Remember that your doctor has prescribed this medicine only for you or your child. Never give it to anyone else.

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects. MONTAS 10 is generally well-tolerated. In studies, the most common side effects reported were abdominal pain, headache, thirst, diarrhea, hyperactivity, asthma, scaly and itchy skin, and rash. These were usually mild and occurred as often in patients treated with MONTAS 10 or placebo (a pill containing no medication).

Additionally, the following have been reported:

- upper respiratory infection
- increased bleeding tendency
- allergic reactions [including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing), hives, rash, and itching]
- behavior and mood related changes [agitation including aggressive behavior or hostility, depression, disorientation, disturbance in attention, dream abnormalities, feeling anxious, hallucinations, insomnia, irritability, memory impairment, restlessness, sleep walking, suicidal thoughts and actions, tremor]
- dizziness, drowsiness, pins and needles/numbness, very rarely seizure
- palpitations
- nose bleed
- diarrhea, dyspepsia, nausea, vomiting
- hepatitis
- bruising, severe skin reactions (erythema multiforme) that may occur without warning
- joint pain, muscle aches and muscle cramps
- bedwetting in children
- weakness/tiredness

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- swelling
- fever

Tell your doctor or pharmacist if you or your child develops any unusual symptom, or if any known symptom continues or worsens.

Tell your healthcare provider right away if you notice any of the following behavior and mood-related changes:

- Obsessive-compulsive symptoms

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

How can I learn more about MONTAS 10 and the condition for which it was prescribed?

You may obtain further information from your physician or pharmacist, who have more detailed information about MONTAS 10 and your condition.

Storage and disposal of MONTAS 10

Storage

Do not store above 30°C.

Store in the original package in order to protect from light and moisture.

Keep out of the reach and sight of children.

Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

Montas 10 is beige coloured, rounded square, biconvex, film coated tablet debossed “M10” on one side and plain on other side, which is packed in aluminium-aluminium blister pack

containing printed aluminium blister foil on one side and plain aluminium blister foil on other side.

Ingredients

Active ingredient

Montelukast Sodium

Inactive ingredient

Microcelac 100 (Lactose monohydrate + Cellulose microcrystalline)

Low substituted HPC

Croscarmellose sodium Magnesium

Stearate

Hydroxy propyl cellulose

Hypromellose 6CPS

Titanium dioxide

Poly Ethylene Glycol 6000

Iron oxide yellow

Iron oxide red

Purified water

MAL NO:

Manufacturer:

Intas Pharmaceuticals Limited
Camp Road, Selaqui, Dehradun,
Uttarakhand, IN 248197, India

Product

Registration Holder:

Accord Healthcare Sdn Bhd
Suite 12A-15, Level 12A, Wisma
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Lumpur, Malaysia

Serial Number: NPRA (R2)

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