

# MONTAS (Montelukast Paediatric Chewable Tablets)

Montelukast Sodium (4mg, 5mg)

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## What MONTAS is used for

MONTAS (montelukast sodium) is used to treat:

- Asthma, including preventing your asthma symptoms during the day and night. MONTAS 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.

## How MONTAS works

MONTAS 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

- When you must not use it

- Do not take MONTAS if you or your child is 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.

## Use in breast-feeding

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

- Before you start to use it

Tell your doctor (or health care provider) about any medical problems or allergies you or your child has now or has had.

- Taking other medicines

In general, MONTAS does not interfere with other medicines that you or your child may be taking. However, some medicines may affect how MONTAS works, or MONTAS may affect how your other medicines work. It is important to tell your doctor about all drugs 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?

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

## How to use MONTAS

### -How much to use

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

- The dose for children 6 to 14 years old for the treatment of asthma and/or allergic rhinitis is one 5-mg chewable tablet daily.
- The dose for children 2 to 5 years old for the treatment of asthma and/or allergic rhinitis is one 4-mg chewable tablet daily.

**-When to use it**

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

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

**- How long to use it**

Do not use this medicine after the date shown following Exp. Dt. on the container.

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

MONTAS 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 as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one tablet or packet once daily.

**- If you use too much (overdose)**

Contact your doctor immediately.

**While you are using it**

**- Things you must do**

It is important that you or your child continue taking MONTAS 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 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. If you or your child experience these changes while taking MONTAS (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 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 is generally well-tolerated. The most common side effects reported were abdominal pain, headache, thirst, diarrhea, hyperactivity, asthma, scaly and itchy skin, and rash. These were usually mild. 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, weakness/tiredness, swelling, fever.

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

-Obsessive-compulsive disorder.

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

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers -> Reporting Side Effects to Medicines

**Storage and disposal of MONTAS**

- 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 4:**

Pink coloured, mottled, oval, biconvex, uncoated tablet, debossed "M4" on one side and plain on other side.

**MONTAS 5:**

Pink coloured, mottled, round, biconvex, uncoated tablet, debossed "M5" on one side and plain on other side.

- Ingredients

- Active Ingredient  
Montelukast Sodium

- Inactive Ingredients  
Mannitol  
Microcrystalline Cellulose  
Croscarmellose sodium  
Aspartame  
Cherry Flavour  
Iron Oxide Red  
Magnesium stearate

**MAL NO:**

MONTAS 4: MAL17065014AZ

MONTAS 5: MAL17065015AZ

**Manufacturer:**

INTAS PHARMACEUTICAL LIMITED

Camp road, Selaqui-248197, Dehradun, Uttarakhand (India).

**Product Registration Holder:**

Accord Healthcare Sdn. Bhd.

Suite 12A-15, Level 12A,

Wisma Zelan

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Bandar Tun Razak

56000 Kuala Lumpur

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01.08.2023

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