

M-KAST 10 (Montelukast Tablets 10mg)

Montelukast Sodium Tablets (10mg)

What is in this leaflet

1. What M-KAST 10 is used for
2. How M-KAST 10 works
3. Before you use M-KAST 10
4. How to use M-KAST 10
5. While you are using it
6. Side effects
7. Storage and Disposal of M-KAST 10
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What is M-KAST 10 used for

Montelukast sodium is the active ingredient in M-KAST 10. It is used as a prevention and also as a treatment for chronic asthma in adults and adolescents from 15 years old onwards.

It is also used for the relief of daytime and night-time symptoms of seasonal allergic rhinitis in adults and adolescents from 15 years old onwards.

How M-KAST 10 works

Montelukast 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 M-KAST 10

-When you must not use it

You must not use this product if you are hypersensitive to active ingredient or excipients of this product.

-Before you start to use it

Tell your doctor about any medical problems or allergies you have now or have had. If your asthma or breathing gets worse, tell your doctor immediately.

This product is not meant to treat acute asthma attacks. Please follow doctor's instructions in case you have an acute asthma attack.

Do not take this medication if your doctor has not prescribed it to you. This medication is not meant to substitute current medications that your doctor has prescribed to you.

Please consult your doctor if you experience symptoms such as a flu-like illness, numbness of arms or legs, worsening of your asthma condition or a rash while on this medication.

Montelukast may be administered with other therapies routinely used in the prevention and treatment of chronic asthma.

Pregnancy and lactation:

If you are pregnant or intend to start a family, please consult your doctor prior to taking this medication. It is not well known if Montelukast appears in breastmilk. Please consult your doctor first before you breastfeed your child while on this medication.

-Taking other medications

Care should be taken if you are taking the medicines listed below before starting M-KAST 10:

- Gemfibrozil (used to treat high cholesterol levels)
- Prednisolone (a steroid drug usually given to reduce inflammation)
- Repaglinide (used in treating diabetes)
- Phenytoin and phenobarbital (used to treat epilepsy)
- Rifampin (an antibiotic)

If you are on these medications or other medications not listed here, please inform your doctor first before taking M-KAST 10 as they may have adverse interactions with each other.

How to use M-KAST 10

-How much to use

Take M-KAST 10 exactly as how your doctor has told you to.

The usual dose for M-KAST 10 is one tablet daily with or without food for adults and adolescents from 15 years old onwards.

-When to use it

It is generally recommended to take your dose in the evening unless your doctor has told you otherwise.

-How long to use it

Use this medication for as long as your doctor's recommendation. Montelukast can treat your asthma only if you continue to take it. Do not stop taking this medication without consulting your doctor first.

You are advised to continue taking this medication even if your asthma is under control as well as during periods of worsening asthma.

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

-If you forget to use it

Please take this medication as prescribed. However, if you missed a dose, just resume the usual schedule of one tablet once daily with or without food. Do not double up the dose to make up for the missed dose.

-If you use too much (overdose)

If you have taken too much of this medication or suspect that you may have overdosed, please contact a doctor immediately.

There were no side-effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in

M-KAST 10 (Montelukast Tablets 10mg)

Montelukast Sodium Tablets (10mg)

adults and children included abdominal pain, sleepiness, thirst, headache, vomiting and hyperactivity.

While you are using it

-Things you must do

If you feel unwell or if you have concerns about a side-effect, you will need to seek advice from your doctor or pharmacist. If you feel very ill, get medical help straight away.

-Things you must not do

Do not use M-KAST 10 after its expiry date, which can be found stated on the blister or box after EXP. The expiry date refers to the last date of the month.

Do not share this medication with anyone, even if they have the same condition or symptoms as you. This medication has been specially prescribed to you only by your doctor or pharmacist.

-Things to be careful of

Driving and using machines:

M-KAST 10 is not expected to affect your ability to drive or operate machinery. In very rare cases, drowsiness or dizziness may occur. If you experience drowsiness or dizziness while on this medication, you are advised not to drive or operate machinery. Consult your doctor regarding the matter.

Side effects

Like all medications, M-KAST 10 has side-effects although not everybody experiences them. If you experience any side-effects, please seek advice from your doctor or pharmacist as soon as possible.

The most common side effects reported were abdominal pain, headache, thirst, diarrhoea, hyperactivity, asthma, scaly and itchy skin and rash.

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]
- Behaviour and mood related changes [agitation including aggressive behaviour 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
- Diarrhoea, 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 doctor or pharmacist if you or your child develops any unusual symptoms, or if any known symptom continues or worsens.

Tell your healthcare provider right away if you notice any of the following behaviour 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 npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of M-KAST 10

-Storage

Store below 30°C. Protect from light and moisture.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose expired medicine or medicines no longer required. These measures will help to protect the environment from pollution.

Product Description

-What it looks like

Beige, rounded square shaped, film-coated tablets debossed with 'X' on one side and '54' on the other side.

-Ingredients

- Active ingredient(s)

Montelukast Sodium

- Inactive ingredient(s)

Hydroxy propyl cellulose, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, opadry yellow, purified water

-MAL number

MAL18046158AZ

M-KAST 10 (Montelukast Tablets 10mg)

Montelukast Sodium Tablets (10mg)

Manufacturer

Aurobindo Pharma Limited

Unit-VII (SEZ), Survey No. 411/P,
425/P, 434/P, 435/P & 458/P, Plot
No. S1 (Part) Special Economic
Zone (Pharma), TSIIC, Green
Industrial Park, Polepally Village,
Jedcherla Mandal, Mahaboobnagar
District, Telangana State 509302,
India

Product Registration Holder

Healol Pharmaceuticals Sdn Bhd

74-3, Jalan Wangsa Delima 6,
KLSC Wangsa Maju,
53300 Kuala Lumpur, Malaysia

Date of revision

-01/06/2020

Serial Number

NPRA(R2/1)200519/442