

MONKASTA FILM-COATED TABLETS

Montelukast (10mg)

Consumer Medication Information Leaflet (RiMUP)

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What *Monkasta* is used for

Monkasta is used for the treatment of adult patients and adolescents, aged 15 years and older with asthma, who are not adequately controlled on their asthma medications and need additional therapy.

For patients with asthma and seasonal allergies, *Monkasta* also treats your seasonal allergy symptoms.

Monkasta also helps prevent asthma symptoms in adult patients and adolescents, aged 15 years and older, which are triggered by exercise.

How *Monkasta* works

The active ingredient in *Monkasta* 10 mg tablets is montelukast, which is a leukotriene receptor antagonist. It blocks naturally occurring chemicals in the lungs called leukotrienes which cause narrowing of the airways and inflammation in the lungs, which can lead to asthma symptoms. Leukotrienes also contribute to the symptoms of allergy. Blocking leukotrienes reduces the symptoms of seasonal allergy (also known as seasonal allergic rhinitis or hay fever).

Before you use *Monkasta*

- When you must not use it

Do not take *Monkasta* if you are allergic (hypersensitive) to montelukast or any of the other ingredients of *Monkasta*.

Monkasta 10 mg tablets are not recommended for use in children under 15 years of age.

- Before you start use it

Patients should be advised never to use oral montelukast to treat acute asthma attacks and to keep their usual appropriate rescue medication for this

purpose readily available. If an acute attack occurs, a short-acting inhaled beta-agonist should be used. Patients should seek their doctor's advice as soon as possible if they need more inhalations of short-acting beta-agonists than usual.

Montelukast should not be substituted for inhaled or oral corticosteroids.

There are no data demonstrating that oral corticosteroids can be reduced when montelukast is given concomitantly.

In rare cases, patients on therapy with anti-asthma agents including montelukast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition which is often treated with systemic corticosteroid therapy. These cases usually, but not always, have been associated with the reduction or withdrawal of oral corticosteroid therapy. The possibility that leukotriene receptor antagonists may be associated with emergence of Churg-Strauss syndrome can neither be excluded nor established. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. Patients who develop these symptoms should be reassessed and their treatment regimens evaluated.

Treatment with montelukast does not alter the need for patients with aspirin-sensitive asthma to avoid taking aspirin and other non-steroidal anti-inflammatory drugs.

Special information about some of the ingredients

Monkasta contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this drug.

Pregnancy: Women who are pregnant, intend to become pregnant or think they might be pregnant should consult their doctor before taking *Monkasta*.

Breast feeding: It is not known whether montelukast is present in human breast-

milk. You should consult your doctor before taking *Monkasta* if you are breast feeding a baby, or intend to breast feed.

Product name} is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects that have been reported very rarely with *Monkasta* may affect some patients' ability to drive or operate machinery.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

In particular, tell your doctor if you are taking phenobarbital or phenytoin (used for treatment of epilepsy), or rifampicin (used to treat tuberculosis and some other infections) because they may decrease the efficacy of *Monkasta*.

Monkasta may be used together with other medicines that you may be taking for asthma.

How to use *Monkasta*

Always take *Monkasta* exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- How much to use

The usual dose for adults and adolescents aged 15 years upwards is one 10 mg tablet daily.

- When to use it

Take *Monkasta* in the evening, with or without food, as instructed by your doctor.

- How long to use it

It is important to continue taking *Monkasta* in the presence or absence of symptoms, for as long as your doctor prescribes it, in order to help maintain control of your asthma. *Monkasta* can treat asthma only with continued use.

- If you forget to use it

If you forget to take a tablet, just carry on with the next one as usual. Do not take an extra tablet to make up; just resume the usual schedule of one tablet, once daily.

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- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

In most cases, no side effects have been reported. The most common symptoms that were reported included the following: thirst, sleepiness, headache, hyperactivity and abdominal pain.

- If you stop taking it

Monkasta can treat your asthma only if you continue to take it.

It is important to continue taking Monkasta for as long as your doctor prescribes. It will help control your asthma.

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

While you are using it

- Things you must do

It is important that you take the medicine as prescribed by the doctor, even if you have no symptoms or if you experience an asthma attack.

If you need to use your beta-agonist inhaler (also known as a bronchodilator or reliever inhaler) more often than usual, you should consult your doctor as soon as possible.

Patients with aspirin-sensitive asthma taking Monkasta must continue to avoid taking aspirin or other non-steroidal anti-inflammatory drugs.

- Things you must not do

Monkasta should not replace steroid medications (whether inhaled or taken by mouth) that you may be already using.

Monkasta tablets should not be used together with other products that contain the same active ingredient, montelukast.

- Things to be careful of

A rare condition has been seen in a very small number of patients taking asthma medications, including montelukast, although montelukast has not been shown to cause it. Seek medical

attention immediately if you experience a combination of any of the following symptoms, particularly if they are persistent or worsening:

- flu-like illness,
- increasing breathlessness,
- pins and needles or numbness of limbs, and/or rash.

Important information about some of the ingredients of Monkasta

Monkasta contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Side effects

Like all medicines, *Monkasta* can cause side effects, although not everybody gets them.

The most commonly reported side effects are:

- abdominal pain
- headache

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

- obsessive-compulsive symptoms.

Additionally, while the medicine has been on the market, the following have been reported:

- upper respiratory infection
- increased bleeding tendency, thrombocytopenia
- allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- behaviour and mood related changes [dream abnormalities, including nightmares, hallucinations, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, tremor, depression, trouble sleeping, sleepwalking, suicidal thoughts and actions (in very rare cases)]
- dizziness, drowsiness, pins and needles/numbness, seizure
- palpitations
- nosebleed
- diarrhoea, dry mouth, indigestion, nausea, vomiting
- hepatitis (inflammation of the liver)
- bruising, itching, hives, tender red lumps under the skin most

commonly on your shins (erythema nodosum),

- joint or muscle pain, muscle cramps
- tiredness, feeling unwell, swelling, fever

In asthmatic patients treated with montelukast, very rare cases of a 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) have been reported. You must tell your doctor right away if you get one or more of these symptoms.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Monkasta

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

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

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- 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

The film-coated tablets are apricot-coloured, round, slightly biconvex, with bevelled edges.

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Supply

Blister pack of 28 film-coated tablets in a box.

- Ingredients

Active ingredient:

Each film-coated tablet contains 10 mg montelukast (equivalent to 10.4 mg montelukast sodium).

Inactive ingredients:

Lactose monohydrate, cellulose, powdered, cellulose, microcrystalline, croscarmellose sodium, magnesium stearate in the table core and hypromellose (E464), titanium, dioxide (E171), talc, propylene glycol, red iron oxide (E172), yellow iron oxide (E172) in the film-coating.

- MAL number:

MAL14010004AZ

Manufacturer

KRKA, d.d., Novo mesto,
Šmarješka cesta 6
8501 Novo mesto,
Slovenia

Product Registration Holder

PAHANG PHARMACY SDN. BHD.
Lot 5979, Jalan Teratai
5 ½ Miles, Off Jalan Meru
41050 Klang, Selangor
Malaysia

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