

MONKASTA CHEWABLE TABLETS

Montelukast (4mg, 5mg)

Consumer Medication Information Leaflet (RiMUP)

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What *Monkasta* is used for

Monkasta chewable tablets is used for the treatment for 2 to 14 years old patients who are not adequately controlled on their medication and need additional therapy.

Monkasta chewable tablets may also be used as an alternative treatment to inhaled corticosteroids for 2 to 14 years old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.

Monkasta chewable tablets also helps prevent the narrowing of airways triggered by exercise for patients 2 to 14 years old.

4 mg chewable tablets are available for paediatric patients 2 to 5 years of age.
5 mg chewable tablets are available for paediatric patients 6 to 14 years of age.

Your doctor will determine how *Monkasta* should be used depending on the symptoms and severity of your child's asthma.

How *Monkasta* works

Monkasta is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, *Monkasta* improves asthma symptoms and helps control asthma.

Before you use *Monkasta*

- When you must not use it

Do not take *Monkasta* if you or your child are allergic (hypersensitive) to montelukast or any of the other ingredients of *Monkasta* (see 6. Further information).

Safety and efficacy of chewable tablets have not been established in the

paediatric population below 2 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 abruptly 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.

Pregnancy: Women who are pregnant, intend to become pregnant or think they might be pregnant should consult their doctor before taking *Monkasta*. Your doctor will assess whether you can take *Monkasta* during this time.

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.

Subsections pregnancy and breast feeding are not applicable for the *Monkasta* 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

Monkasta 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.

This subsection is not applicable for the *Monkasta* 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

- Taking other medicines

Some medicines may affect how *Monkasta* works, or *Monkasta* may affect how your child's other medicines work.

Please tell your doctor or pharmacist if you or your child is taking or has recently taken other medicines, including those obtained without a prescription.

Tell your doctor if you or your child is taking the following medicines before starting *Monkasta*:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)

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

You or your child 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.

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. To be taken by mouth.

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- How much to use

Children 2 to 5 years of age

- This medicine is to be given to a child under adult supervision.
- One 4 mg chewable tablet daily to be taken in the evening.

Children 6 to 14 years of age

- One 5 mg chewable tablet daily to be taken in the evening.

- When to use it

Monkasta chewable tablets can be taken with or without food.

- 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

Try to take Monkasta as prescribed. However, if you or your child misses 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 or your child use too much (overdose)

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 or your child stops taking Monkasta

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

It is important to continue taking Monkasta for as long as your doctor prescribes. It will help control you or your child's asthma.

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

While you are using it

- Things you must do

If your child's asthma or breathing gets worse, tell your doctor immediately.

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 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 aspartame, a source of phenylalanine. May be harmful for children with phenylketonuria.

Side effects

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

For Monkasta 4 mg chewable tablet, the most commonly reported side effect thought to be related to treatment with montelukast were:

- Abdominal pain
- Thirst.

For Monkasta 5 mg chewable tablet, the most commonly reported side effect thought to be related to montelukast was:

- Headache

These were usually mild and occurred with the same frequency in patients treated with montelukast or placebo (tablets that do not contain any active substance).

Tell your healthcare provider right away if you notice any of the following behavior 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
- diarrhea, 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 your child gets 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.

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

Storage and Disposal of Clopilet

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

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

Monkasta chewable tablets 4 mg are presented as pink, marbled, round, slightly biconvex tablets with bevelled edges and inscription 4 on one side.

Monkasta chewable tablets 5 mg are presented as pink, marbled, round, slightly biconvex tablets with bevelled edges and inscription 5 on one side.

Supply

Blister pack of 28 chewable tablets in a box.

- Ingredients

Active ingredient:

Each chewable tablet contains 5 mg montelukast (equivalent to 5.20 mg montelukast sodium).

Each chewable tablet contains 4 mg montelukast (equivalent to 4.16 mg montelukast sodium).

Inactive ingredients:

mannitol (E421), cellulose, microcrystalline, croscarmellose sodium, hydroxypropylcellulose, aspartame (E951), red iron oxide (E172), flavour cherry black, magnesium stearate

- MAL numbers:

4 mg: MAL14010002AZ

5 mg: MAL14010003AZ

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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26/08/2020

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