

Moncas

PACKAGE LEAFLET: INFORMATION FOR THE USER

Moncas
5 mg chewable tablets
Montelukast

Read all of this leaflet carefully before you or your child start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you or your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours or your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What MONCAS is and what it is used for
2. Before you take MONCAS
3. How to take MONCAS
4. Possible side effects
5. How to store MONCAS
6. Further information

1. WHAT MONCAS IS AND WHAT IT IS USED FOR

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

Your doctor has prescribed MONCAS to treat asthma, preventing your asthma symptoms during the day and night.

- MONCAS is used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
- MONCAS may also be used as an alternative treatment to inhaled corticosteroids for 6 to 14 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
- MONCAS also helps prevent the narrowing of airways triggered by exercise.

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

What is asthma?

Asthma is a long-term disease.

Asthma includes:

- difficulty breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions.
- sensitive airways that react to many things, such as cigarette smoke, pollen, cold air, or exercise.
- swelling (inflammation) in the lining of the airways.

Symptoms of asthma include: Coughing, wheezing, and chest tightness.

2. BEFORE YOU TAKE MONCAS

Tell your doctor about any medical problems or allergies you or your child has now or has had.

Do not take MONCAS if you or your child

- is allergic (hypersensitive) to montelukast or any of the other ingredients of MONCAS (see 6. Further information).

Take special care with MONCAS

- If you or your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral MONCAS is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you or your child. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you or your child take all asthma medications prescribed by your doctor. MONCAS should not be used instead of other asthma medications your doctor has prescribed for you or your child.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- 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.

Use in children

For children 2 to 5 years old, MONCAS 4 mg chewable tablets are available.

For children 6 to 14 years old, MONCAS 5 mg chewable tablets are available.

Taking other medicines

Some medicines may affect how MONCAS works, or MONCAS may affect how 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 MONCAS:

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

Taking MONCAS with food and drink

MONCAS 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking MONCAS. Your doctor will assess whether you can take MONCAS during this time.

Use in breast-feeding

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

Driving and using machines

MONCAS is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with MONCAS may affect some patients' ability to drive or operate machinery.

Important information about some of the ingredients of MONCAS

MONCAS chewable tablets contain aspartame, a source of phenylalanine. If your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that each MONCAS 5 mg chewable tablet contains phenylalanine (equivalent to 0.842 mg phenylalanine per 5 mg chewable tablet).

3. HOW TO TAKE MONCAS

- You or your child should take only one tablet of MONCAS once a day as prescribed by your doctor.
- It should be taken even when you or your child has no symptoms or has an acute asthma attack.
- Always take MONCAS as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- To be taken by mouth

For children 6 to 14 years of age:

One MONCAS 5 mg chewable tablet daily to be taken in the evening. MONCAS 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food. The tablets are to be chewed before swallowing.

If you or your child is taking MONCAS, be sure that you or your child does not take any other products that contain the same active ingredient, montelukast.

If you or your child takes more MONCAS than you should

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 forget to take MONCAS or give MONCAS to your child

Try to take MONCAS 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 stops taking MONCAS

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

It is important to continue taking MONCAS 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 doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

In clinical studies with MONCAS 5 mg chewable tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 paediatric patients treated) thought to be related to MONCAS were:

- headache

Additionally, the following side effect was reported in clinical studies with MONCAS 10 mg film-coated tablets:

- abdominal pain

These were usually mild and occurred at a greater frequency in patients treated with MONCAS than placebo (a pill containing no medication).

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects at least 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Very rare (affects less than 1 user in 10,000)

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

- upper respiratory infection (*Very common*)
- increased bleeding tendency (*Rare*)
- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (*Uncommon*)
- behaviour and mood related changes [dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression (*Uncommon*); tremor, disturbance in attention, memory impairment (*Rare*); hallucinations, disorientation, suicidal thoughts and actions (*Very rare*)]
- dizziness, drowsiness, pins and needles/numbness, seizure (*Uncommon*)
- palpitations (*Rare*)
- nosebleed (*Uncommon*), swelling (inflammation) of the lungs (*Very rare*)
- diarrhoea, nausea, vomiting (*Common*); dry mouth, indigestion (*Uncommon*)
- hepatitis (inflammation of the liver) (*Very rare*)
- rash (*Common*); bruising, itching, hives (*Uncommon*); tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning (*Very rare*)
- joint or muscle pain, muscle cramps (*Uncommon*)
- fever (*Common*); weakness/tiredness, feeling unwell, swelling (*Uncommon*)

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.

Reporting of side effects

If you or your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MONCAS

- Keep out of the reach and sight of children.
- Do not use this medicine after the expiry date which is stated on the carton and on the blister after EXP. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from light and moisture.
- 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.

6. FURTHER INFORMATION

What MONCAS contains

- The active substance is montelukast. Each tablet contains montelukast sodium which corresponds to 5 mg of montelukast.
- The other ingredients are: mannitol, microcrystalline cellulose, hydroxypropyl cellulose, iron oxide red, croscarmellose sodium, cherry flavour, aspartame and magnesium stearate.

What MONCAS looks like and contents of the pack

MONCAS 5 mg chewable tablets are pink, flat, round tablets with beveled edges

Blisters in packages of: 14, 28 and 98 chewable tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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