

Moncas

PACKAGE LEAFLET: INFORMATION FOR THE USER

Moncas

10 mg film-coated tablets

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

- Keep this leaflet. You may need to read it again.
 - If you have any further questions, ask your doctor or pharmacist.
 - This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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 your lungs and also cause allergy symptoms. By blocking leukotrienes, Moncas improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

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 also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Moncas is indicated in asthma, Moncas can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Moncas should be used depending on the symptoms and severity of your 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.

What are seasonal allergies?

Seasonal allergies (also known as hay fever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds. The symptoms of seasonal allergies typically may include: stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes.

2. BEFORE YOU TAKE MONCAS

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

Do not give Moncas if you

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

Take special care with Moncas

- If your 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. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you take all asthma medications prescribed by your doctor. Moncas should not be substituted for other asthma medications your doctor has prescribed for you.
- 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 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 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.

Please tell your doctor if you are 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)
- gemfibrozil (used for treatment of high lipid levels in plasma)

Taking Moncas with food and drink

Moncas 10 mg film-coated tablets may be taken with or without 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 contain aspartame, a source of phenylalanine. If you suffer from phenylketonuria (a rare, hereditary disorder of the metabolism) you should take this into account.

3. HOW TO TAKE MONCAS

- You should take only one tablet of Moncas once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have 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 adults 15 years of age and older:

One Moncas 10 mg film-coated tablet daily to be taken in the evening. Moncas 10 mg film-coated tablets may be taken with or without food.

If you are taking Moncas, be sure that you do not take any other products that contain the same active ingredient, montelukast.

If you take 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

Try to take Moncas as prescribed. However, if you miss 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 stop taking Moncas

Moncas can treat your asthma only if you continue to take it. It is important to continue taking Moncas or 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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

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

- headache
- abdominal pain

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

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

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)

- 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, sleep walking, 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.

Ask your doctor or pharmacist for more information about side effects. 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.

5. HOW TO STORE MONCAS

Keep out of the reach and sight of children.

Do not use Moncas 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.

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 10 mg of montelukast.
- The other ingredients are: mannitol, microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium, banana flavour, aspartame (E 951), magnesium stearate. In addition the coating of the tablets contains Opadry yellow 20A33251 (which consists of: hypromellose, hydroxypropylcellulose, talc, titanium dioxide, iron oxide yellow and iron oxide red).

What Moncas looks like and contents of the pack

Moncas 10 mg film-coated tablets are beige, round and biconvex.

Blisters in packages of: 14,28 and 98 Film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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