

MONTEMAC 4

(Montelukast Chewable Tablets 4 mg)

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What MONTEMAC 4 is used for

MONTEMAC 4 is used for the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older. Montelukast is indicated in adults and pediatric patients 2 years of age and older for the relief of daytime and nighttime symptoms of seasonal allergic rhinitis.

How MONTEMAC 4 works

MONTEMAC 4 is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, MONTEMAC 4 improves asthma symptoms and helps control asthma.

Before you use MONTEMAC 4

When you must not take it

Do not take Montelukast Tablet if your child is allergic (hypersensitive) to montelukast or any of the other ingredients of MONTEMAC 4.

Before you start to take it

If your child's asthma or breathing gets worse, tell your doctor immediately. Oral MONTEMAC 4 is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given your child. Always have your child's inhaled rescue medicine for asthma attacks with you.

It is important that your child take all asthma medications prescribed by your doctor. MONTEMAC 4 should not be used instead of other asthma medications your doctor has prescribed for your child.

Any patients on anti-asthma medicines should be aware that if your child develops 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 child's doctor.

Your child should not take acetylsalicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your child's asthma worse.

Taking other medicines

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Tell your doctor if you are taking the following medicines:

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

How to use MONTEMAC 4

This medicine is to be given to a child under adult supervision. Your child should take only one tablet of MONTEMAC 4 once a day as prescribed by your doctor. It should be given even when your child has no symptoms or has an acute asthma attack.

Always give MONTEMAC 4 as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. To be taken by mouth.

How much to take

One MONTEMAC 4 daily to be given in the evening. It should not be given immediately with food; it should be given at least 1 hour before or 2 hours after food. The tablets are to be chewed before swallowing.

If your child is taking MONTEMAC 4, be sure that your child does not take any other products that contain the same active ingredients, montelukast. It is not recommended below 2 years of age.

If you forget to take it

Try to give MONTEMAC 4 as prescribed. However, if you miss a dose of your child, just resume the usual schedule of one tablet once daily. Do not give a double dose to make up for a forgotten dose.

If you stop taking it

MONTEMAC 4 can treat your child's asthma only if your child continues to take it. It is important to continue giving MONTEMAC 4 for as long as your doctor prescribes. It will help control your child's asthma. If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you take 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.

While you are using it

Things you must do

It should be given at least 2 hour before or 2 hours after food.

Things you must not do

Driving and using machines. This subsection is not applicable for MONTEMAC 4 since they are intended for use in children 2 to 5

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years of age, however the following information is relevant to the active ingredients, montelukast. Montelukast is not expected to affect the ability to drive a car or operate machinery. However, individual response to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with Montelukast may affect some patient's ability to drive or operate machinery.

Things to be careful of

Pregnancy and breast-feeding. Use in pregnancy. Women who are pregnant or intend to become pregnant should consult their doctor before using Montelukast. The doctor will assess whether such patient can take Montelukast during this time. Use in breast-feeding. It is not known if Montelukast appears in breast milk. The patient who is breast-feeding or intend to breast-feed, should consult with the doctor before taking Montelukast.

Side Effects

Like all medicines, MONTEMAC 4 can cause side effects, although not everybody gets them. With Montelukast, the most commonly reported side effects are headache, thirst and abdominal pain. 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 difficulty in breathing or swallowing.
- behaviour and mood related changes [dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression ; tremor, disturbance in attention,

memory impairment ; hallucinations, disorientation, suicidal thoughts and actions.

- dizziness, drowsiness, pins and needles/numbness, seizure
- palpitations
- Nosebleed, swelling (inflammation) of the lungs, diarrhoea, nausea, vomiting; dry mouth, indigestion.
- hepatitis (inflammation of the liver)
- rash
- Bruising, itching, hives; tender red lumps under the skin most commonly on your child's shins (erythema nodosum). severe skin reactions (erythema multiforme) that may occur without warning
- joint or muscle pain, muscle cramps
- fever
- weakness/tiredness, feeling unwell, swelling

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 get one or more of these symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of MONTEMAC 4:

Storage

Store below 30°C in a dry place, Protect from moisture & light. Keep out of the reach and sight of children.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away the medicines you no longer use. These measures will help to protect the environment.

Product Description:

What it looks like

Pink color, oval, biconvex, uncoated chewable mottle tablet debossed with 'CL 55' on one side and plain on other side. Available as Alu/Alu Blister pack of 10 Tablets. Such 10 blisters are packed in a carton along with a pack insert.

Ingredients

Active ingredients
Montelukast Sodium

Inactive ingredients:

Microcrystalline Cellulose (Avicel PH 101); Mannitol ; Croscarmellose Sodium (Ac-di-sol) Ferric Oxide Red ; Hydroxypropyl Cellulose (Klucel EF); Disodium Edetate; Aspartame; Cherry Flavour flavour (FL SD # 594) Magnesium Stearate (Vegetable grade) & Purified Water

MAL Number(s):

MAL No: *****

Manufacturer

Macleods Pharmaceuticals Ltd
Village Theda, Post Office
Lodhimajra, Tehsil Baddi, District
Solan, Himachal Pradesh 174101
India

Product Registration Holder

Biocare Pharmaceutical (M) Sdn
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Date of Revision

21/09/2017