

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Read this entire leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet.

**In this leaflet:**

1. What Montelukast Tablet 10mg is and what it is used for
2. What you need to know before you take Montelukast Tablet
3. How to take Montelukast Tablet 10mg
4. Possible side effects
5. How to store Montelukast Tablet 10mg
6. Further information

**1. WHAT MONTELUKAST TABLET 10MG IS AND WHAT IT IS USED FOR**

Montelukast Tablet is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs & also cause allergy symptoms. By blocking leukotrienes, Montelukast Tablet 10 mg improves asthma symptoms and helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

Your doctor has prescribed to you Montelukast Tablet 10 mg to treat asthma, preventing your asthma symptoms during the day and night.

- Montelukast Tablet 10 mg is used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
- Montelukast Tablet 10 mg also helps prevent the narrowing of airways triggered by exercise.
- It is used in those asthmatic patients in whom Montelukast Tablet 10 mg is indicated in asthma, Montelukast Tablet 10 mg can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Montelukast Tablet 10 mg should be used depending on the symptoms and severity of your asthma.

Montelukast 10 mg film-coated tablets are indicated for patients 15 years of age and older. You must talk to your doctor or pharmacist if you do not feel better or if you feel worse. The product should be used as add-on therapy in those patients with mild to moderate persistent

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asthma who are inadequately controlled on inhaled corticosteroids and in whom "as-needed" short acting fl-agonists provide inadequate clinical control of 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 MONTELUKAST TABLET 10 MG**

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

**Do not take Montelukast Tablet 10 mg if you**

- are allergic (hypersensitive) to montelukast or any of the other ingredients of Montelukast Tablet 10 mg.

**Take special care with Montelukast Tablet 10 mg**

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast Tablet 10 mg is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given to 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. Montelukast Tablet 10 mg should not be used instead of 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.

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

**Children and adolescents:**

Montelukast 10 mg film-coated tablets are not recommended for use in children and adolescents under the age of 15

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

For children and adolescents 6 to 14 years old, Montelukast Paediatric 5 mg chewable tablets are available.

**Taking other medicines**

Some medicines may affect how Montelukast Tablet 10 mg works, or Montelukast Tablet 10 mg may affect how other medicines work.

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

Tell your doctor if you are taking the following medicines before starting Montelukast Tablet 10 mg:

- 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 level in plasma).

**Taking Montelukast Tablet 10 mg with food and drink**

Montelukast Tablet 10 mg can 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 using Montelukast. The doctor will assess whether such patient can take Montelukast during this time.

*Use in breast-feeding*

It is unknown whether montelukast is excreted in human milk. You should consult your doctor before taking Montelukast 10 mg film-coated tablets if you are breast-feeding or intend to breastfeed. Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

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Montelukast is not expected to affect the 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 Montelukast may affect some patient's ability to drive or operate machinery.

**3. HOW TO TAKE MONTELUKAST TABLET 10 MG**

- Always take Montelukast Tablet 10 mg as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- You should take only one tablet of Montelukast Tablet 10 mg once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or has an acute asthma attack.

**For adults and adolescents 15 years of age and older:**

One 10 mg tablet to be taken daily in the evening.

If you are taking Montelukast Tablet 10 mg, be sure that you do not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.

Paediatric population Do not give montemac 10 mg film coated tablets to children less than 15 years of age. The safety and efficacy of Montemac 10 mg film-coated tablets in children less than 15 years has not been established.

Montelukast 10 mg film-coated tablets may be taken with or without food

**If you have taken more Montelukast Tablet 10 mg 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 Montelukast Tablet 10 mg**

Try to take Montelukast Tablet 10 mg as prescribed. However, if you miss a dose of your medicine, 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 stops taking Montelukast Tablet 10 mg**

Montelukast Tablet 10 mg can treat your asthma only if you continue to take it.

It is important to continue take Montelukast Tablet 10 mg 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 or pharmacist.

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**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Montelukast Tablet 10 mg can cause side effects, although not everybody gets them.

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.

With Montelukast, 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 were:

- Headache
- Abdominal pain

These were usually mild and occurred at a greater frequency in patients treated with Montelukast 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)

If any of the following happens, stop taking Montelukast 10 mg and contact a doctor or go to the nearest hospital straight away, as you may need urgent medical attention:

- allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (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)
- suicidal thoughts and actions (very rare)

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

Very common: may affect more than 1 in 10 people

- upper respiratory infection

Common: may affect up to 1 in 10 people

- diarrhoea, nausea, vomiting

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- rash
- fever

Uncommon: may affect up to 1 in 100 people

- behaviour and mood related changes [dream abnormalities, including nightmares, troublesleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression]
- dizziness, drowsiness, pins and needles/numbness, seizure nosebleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- weakness/tiredness, feeling unwell, swelling

Rare: may affect up to 1 in 1,000 people

- increased bleeding tendency
- disturbance in attention, memory impairment
- palpitations
- tremor

Very rare: may affect up to 1 in 10,000 people

- hallucinations, disorientation
- hepatitis (inflammation of the liver)
- swelling (inflammation) of the lungs

**Reporting of side effects**

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

**5. HOW TO STORE MONTELUKAST TABLET 10 MG**

Keep out of the reach and sight of children.

**Do not store above 30°C. Protect from moisture.**

**6. FURTHER INFORMATION**

**What Montelukast Tablet 10 mg contains**

Each film coated tablet contains:

Montelukast Sodium USP 10.4 mg equivalent to

Montelukast.....10 mg

**Montemac 10** (Montelukast Sodium Tablet 10 mg)

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**What Montelukast Tablet 10 mg looks like and contents of the pack**

Beige colour, rounded square shaped, biconvex, film coated tablet debossed with 'CL 26' on one side and plain on the other side.

**Product Distribution Category:**

Prescription Only Medicine (POM)

**List of Excipients**

Lactose monohydrate (Pharmatose 200 M), Microcrystalline cellulose, (Avicel PH 101), Croscarmellose sodium (Ac-di-sol), Hydroxypropyl cellulose (Klucel EF), Disodium edentate, Isopropyl alcohol (E-grade)#, Magnesium stearate (vegetable grade), Instacoat Aqua Brown ICG-A-10310^\$, Purified Water.

**Precautionary Statement:**

The tablet contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption should not take this medicine.

**Montemac 10 (Montelukast sodium Tablet 10 mg) will be packed in,**

- 1. (Alu/Alu Blister pack of 3 X 10 tablets)**
- 2. HDPE Container of 30 Tablets**

Following minimum batch details is coded on Blister Strip Aluminium foil.  
Batch No., Mfg. Date and Exp. Date.

**Supplier**

Macleods Pharmaceuticals Ltd.  
304, Atlanta Arcade,  
Marol Church Road,  
Andheri (East)  
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Phone: +91-22-66762800  
Fax: +91-22-2821 6599  
E-mail: [exports@macleodspharma.com](mailto:exports@macleodspharma.com)

**Manufacturer**

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Block N-2, Village: Theda,  
PO: Lodhimajra, Tehsil Baddi,  
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