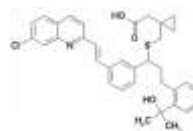


Rx **MONTELUKAST**  
(Montelukast is an oral leukotriene receptor antagonist)



**GENERIC NAME:** montelukast

**DRUG CLASS AND MECHANISM**

Montelukast is an oral leukotriene receptor antagonist for the treatment of asthma and seasonal allergic rhinitis (hay fever). Leukotrienes are a group of naturally occurring chemicals in the body that promote inflammation in asthma and seasonal allergic rhinitis and in other diseases in which inflammation is important (such as allergy). They are formed by cells, released, and then bound to other cells, and it is the binding to these other cells that stimulates the cells to promote inflammation. Montelukast works in a manner similar to zafirlukast (Accolate), blocking the binding of some leukotrienes. Unlike zafirlukast, montelukast does not inhibit CYP2C9 or CYP3A4, two enzymes in the liver that are important in breaking down and eliminating many drugs. Therefore, unlike zafirlukast, montelukast is not expected to affect the elimination of other drugs. The safety and effectiveness of montelukast has been demonstrated in children as young as 6 months of age. It was approved by the FDA in 1998.

**GENERIC AVAILABLE:** Yes

**PRESCRIPTION:** Yes

**PREPARATIONS:** Tablets: 10mg. Chewable tablets: 4mg and 5mg.

**PRESCRIBED FOR**

Montelukast is used for the treatment of asthma and seasonal allergic rhinitis. Montelukast begins working after 3 to 14 days of therapy. Therefore, it should not be used for the treatment of an acute asthmatic attack.

**DOSING**

The recommended dose of montelukast is 4, 5, or 10 mg daily. The 4 and 5 mg tablets are used in children. Montelukast should be taken in the evening with or without food.

**DRUG INTERACTIONS**

Phenobarbital increases the blood concentration of montelukast by about 40%. Rifampin may have the same effect. Therefore, the dose of montelukast may need to be reduced when given concurrently with these drugs.

**USES**

This medication is used to control chronic asthma and help decrease the number of asthma attacks. It is also used to treat hay fever (seasonal allergic rhinitis). This drug improves asthma and hay fever symptoms by blocking substances in the body called leukotrienes.

**HOW TO USE**

Take this medicine as directed, generally 1 tablet (10mg) daily with or without food. Take it in the evening for asthma or at about the same time each day (either morning or evening) for hay fever. If you are using this drug for both asthma and hay fever, take it in the evening. Keep taking this medicine every day, even during asthma attacks and periods when you have no asthma symptoms. This drug does not relieve acute asthma attacks. Use your prescribed acute asthma attack medicines (and pre-exercise medicines for exercise-related asthma) as directed. Consult your doctor or pharmacist for specific advice on your drug therapy. Do not decrease or stop any asthma medicine unless instructed your doctor. Report promptly to your doctor or pharmacist if your asthma symptoms worsen, short-acting inhaler use increases or use exceeds the prescribed 24 hour maximum. This medicine may come with a patient information leaflet. Read it carefully. Ask your doctor, nurse, or pharmacist any questions that you may have about this medicine.

**SIDE EFFECTS**

Unusual weakness, stomach upset, diarrhea, dizziness, cough, headache, nausea, vomiting, trouble sleeping, or mouth pain may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: hallucinations, fever, persistent sore throat or earache, flu symptoms. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: stomach pain, muscle aches/cramps, irregular heartbeat,

yellowing eyes and skin, numbness or tingling of the hands or feet, dull sense of touch, easy bruising or bleeding, swelling, seizures. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, severe swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

**PRECAUTIONS**

Before taking montelukast, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. Before using this drug, tell your doctor or pharmacist your medical history, especially of: liver disease. Use of this medication is not recommended in children less than 15 years old. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug is excreted into breast milk. Consult your doctor before breast-feeding.

**OVERDOSE**

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include thirst, dilated pupils, drowsiness, increased muscle movements, or severe stomach pain.

**MISSED DOSE**

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

**STORAGE**

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in bathroom. Keep all medicines away from children and pets.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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