

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 09/2016

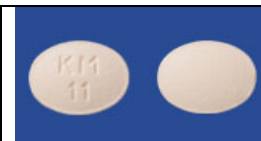
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: MONTELUKAST Tablets 5mg "KM"

Active ingredient: Montelukast sodium

Dosage form: bright grayish yellow tablet, major axis: 7.6mm, minor axis: 5.6mm, thickness: 2.9mm

Print on wrapping: (face)モンテルカスト錠 5mg「KM」, (reverse side)MONTELUKAST Tab.5mg, モンテルカスト錠 5mg「KM」, 5, Kyorin, KM-11



Effects of this medicine

This medicine controls the contraction of bronchi by suppressing the leukotriene action. It helps prevent onset of coughs/wheezing/respiratory distress due to bronchial asthma. Also, it controls nasal ventilation resistance, etc. and improves symptoms of nasal obstruction/nasal discharge/sneezing due to allergic rhinitis.

It is usually used to treat bronchial asthma and allergic rhinitis in preventing purpose. For bronchial asthma, it cannot stop the asthma attack that is already taking place. Use other medicine to stop already occurring attacks.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is<< to be written by a healthcare professional>>
 - For bronchial asthma: In general, for adults, take 2 tablets (10 mg of montelukast) at a time, once a day at bedtime.
 - For allergic rhinitis: In general, for adults, take 1 to 2 tablets (5 to 10 mg of montelukast) at a time, once a day at bedtime.
- In any cases, strictly follow the instructions.
- If you miss a dose, take a dose as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should never take two doses at one time.
 - If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
 - Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, stomachache, nausea, heartburn, headache, hepatic function abnormal, dry mouth, somnolence, gastric discomfort, fatigue, rash and pruritus. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- cold sweat, pale face, respiratory distress [anaphylaxis]
- respiratory distress, swollen face/tongue/throat [angioedema]
- loss of appetite, general fatigue, yellowing of the skin/eyes [fulminant hepatitis, hepatitis, liver dysfunction, jaundice]
- fever, red-eye, rash/red-spots/fluid-filled blisters appear on skin/mucosa [toxic epidermal necrolysis, mucocutaneous ocular syndrome, erythema multiforme]
- bleeding from the nose/gums, bleeding under skin seen in limbs [thrombocytopenia]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of the reach of children. Store away from light, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.