

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

Internal

Revised: 02/2025

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 「OHARA」

Active ingredient: Montelukast Sodium

Dosage form: pale orange tablet, diameter: 6.6 mm, thickness: 3.5 mm

Imprint or print on wrapping: モンテルカスト 5mg「オーハラ」, 成人用,
Montelukast 5mg「OHARA」



Effects of this medicine

This medicine suppresses bronchoconstriction by inhibiting the action of leukotriene. It lessens development of symptoms of bronchial asthma such as cough, wheezing and breathing difficulty. In addition, it controls nasal ventilation resistance etc. and improves symptoms of allergic rhinitis such as nasal congestion, nasal discharge and sneezing.

It is usually used to treat bronchial asthma and allergic rhinitis. This medicine is effective for preventing an asthma attack, not for stopping an asthma attack that has already developed. Use other medicine to stop an asthma attack.

The following patients may need to be careful when 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 or foods.
- 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 before 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 before bedtime.
- Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. However, 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, abdominal pain, nausea, heartburn, headache, liver dysfunction, dry mouth, somnolence, gastric distress, malaise, rash and itch. 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, facial pallor, respiratory distress [anaphylaxis]
- breathing difficulty, swelling of the face/tongue/pharynx [angioedema]
- loss of appetite, general malaise, yellowing of the skin or conjunctiva [fulminant hepatitis, hepatitis, liver dysfunction, jaundice]
- fever, bloodshot eyes, skin/mucosal rash/erythema/blister [toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme]
- subcutaneous bleeding in limbs, nose/gum bleeding [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. If you do not know how to discard, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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