

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

Internal

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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 CHEWABLE TABLETS 5mg 「OHARA」**

**Active ingredient:** Montelukast Sodium

**Dosage form:** pale red tablet, diameter: 9.7 mm, thickness: 4.5 mm

**Print on wrapping:** モンテルカスト chewable 「オーハラ」, 5 mg, 気管支喘息, 小児用, かんでのめる, Montelukast Chewable 5 mg 「OHARA」



**Effects of this medicine**

This medicine controls the contraction of bronchi by suppressing the leukotriene action. It helps prevent onset of coughs/wheezing/breathing difficulty due to bronchial asthma.

It is usually used to treat bronchial asthma. It 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.

**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))
- In general, for children 6 years old or over, take 1 tablet (5 mg as montelukast) at a time, once a day before bedtime, by dissolving or chewing in the mouth. 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 follow your regular dosing schedule. You should not 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**

- The guardian of the patient should closely observe his or her condition. If any abnormality occurs, take proper measures such as contacting your doctor immediately.

**Possible adverse reactions to this medicine**

Commonly reported adverse reactions include hives, dizziness, nausea, headache and eczema. 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 face/tongue/throat [angioedema]
- loss of appetite, general malaise, yellow discoloration of the skin and the conjunctiva [fulminant hepatitis, hepatitis, liver dysfunction, jaundice]
- fever, bloodshot eyes, rash/erythema/blister of the skin/mucosa [toxic epidermal necrosis, mucocutaneous ocular syndrome, erythema multiforme]
- nose bleeding, gum bleeding, subcutaneous bleeding in limbs [decreased platelets]

**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.

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