

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

Internal
Revised: 02/2015

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: SINGULAIR Chewable Tablets 5mg

Active ingredient: Montelukast sodium

Dosage form: pale red tablet, diameter: 9.5mm, thickness: 4.4mm

Print on wrapping: SINGULAIR Chewable 5mg, シングレアチュアブル 5mg, 小児用, 気管支喘息, かんでのめる



Effects of this medicine

This medicine suppresses bronchoconstriction by inhibiting the activity of leukotriene. It prevents episode of bronchial asthma such as cough, wheezing and breathing difficulty.

It is usually used in the treatment of 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 or older, take 1 tablet (5 mg of montelukast) at a time with dissolving or chewing in the mouth once a day at bedtime. Strictly follow the instructions.
- If you miss a dose, take a dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and continue the 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

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

Possible adverse reactions to this medicine

Commonly reported adverse reactions include hives, dizziness, nausea, vomit, headache, tic, eczema, erythema multiform, glow, menstruation disorder, and emotion unstable. 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, breathing difficulty [anaphylaxis]
- breathing difficulty, swelling of the face, tongue, or pharynx [angioedema]
- loss of appetite, general malaise, yellowness in the skin or conjunctiva [fulminant hepatitis, hepatitis, hepatic dysfunction, jaundice]
- fever, ocular hyperemia, skin/mucosal rash, erythema, blister [toxic epidermal necrolysis, Stevens-Johnson 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 it 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.