

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 Tablets 10mg

Active ingredient: Montelukast sodium

Dosage form: bright grayish yellow tablet, diameter: 8.0 mm, thickness: 4.1 mm

Print on wrapping: SINGULAIR 10mg, シングレア 10mg, 成人用, 気管支喘息・アレルギー性鼻炎



Effects of this medicine

This medicine suppresses bronchoconstriction by inhibiting the action of leukotriene. It prevents episode 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 stuffy nose, runny nose, sneezing.

It is usually used in the treatment of bronchial asthma and allergic rhinitis. In 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 >>
 - For treatment of bronchial asthma: In general, for adult, take 1 tablet (10 mg of montelukast) at a time, once a day at bedtime.
 - For treatment of allergic rhinitis: In general, for adult, take 5 to 10 mg of montelukast at a time, once a day at bedtime.
- Each SINGULAIR tablet 10 mg contains 10 mg as montelukast. In both cases, 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, abdominal pain, nausea, heartburn, headache, liver dysfunction, dry mouth, somnolence, stomach discomfort, 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, 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.