

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

620006935

Revised: 02/2012

Information is based on approvals granted in Japan. In some cases, the approved details may vary in countries other than Japan.

In deciding to use a medicine, the risk (side effects) of taking the medicine must be weighed against the benefit (effects) it will do. The patient's cooperation is indispensable here.

Brand name : SINGULAIR Chewable Tablets 5mg

Active ingredient : Montelukast sodium

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

Printings 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, tell your doctor/pharmacist

- If you ever experienced any allergic reaction (itch, rash etc.) to any medicine.
- If you are pregnant or breastfeeding.
- If you are using any other prescription or nonprescription (OTC) medicine. (It is important to reduce the risk of drug interactions.)

Dosage regimen (proper use of this medicine)

- **Your dosage regimen is:** ◀ ◻ ▶ :order of your doctor▶
- General dosage regimen: For children 6 years or older, take 1 tablet (5 mg of the active ingredient) with dissolving or chewing in the mouth once daily at bedtime. Strictly follow the instructions of your doctor/pharmacist.
- Missed dose: Take a dose as soon as possible when you remembered that you missed a dose. However, if it is almost time for the next dose, skip the missed dose and continue the regular dosing schedule. DO NOT take double doses to make up for the missed dose.
- Overdose: If you took too much of the medicine (more than ordered), check with your doctor/pharmacist.
- Others: Do not stop taking the medicine without the instructions of your doctor.

Precautions while using this medicine

- The guardian of the patient should observe him or her. If any abnormality occurs, consult the doctor immediately for proper action.

Side effects of this medicine

Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: diarrhea, abdominal pain, nausea, heartburn, headache, urticarial rash, dizziness, etc.

In rare cases, symptoms described below may be the sign of side effects indicated in brackets []. If they occur, stop taking your medicine and check with your doctor immediately.

- cold sweat, pallor, breathing difficulty [anaphylactic reaction]
- 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]

Other side effects not listed here may occur. Check with your doctor/pharmacist if you have any worrisome symptom.

Storage and other information

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

For doctor use only: Day Month Year

SINGULAIR Chewable Tablets 5mg

For further information, ask your doctor/pharmacist. "Kanjamuke Iyakuhin Guide" and Japanese package insert information (for medical professionals) is available on the website of Pharmaceuticals and Medical Devices Agency.