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: PRANLUKAST TABLETS 112.5mg "CEO"

Active ingredient:Pranlukast hydrate

Dosage form: white to pale yellow tablet, diameter: 7.5 mm, thickness: 2.7 mm

Print on wrapping:(face) プランルカスト112.5mg「CEO」, CEO 131, プランルカスト

112.5mg

(back) PRANLUKAST 112.5mg「CEO」, CEO 131, プランルカスト

112.5mg



Effects of this medicine

This medicine selectively binds to leukotriene receptor and inhibits its action. It consequently suppresses increase in airway contraction, vascular permeability, mucosal edema and hypersensitivity.

It is usually used to treat bronchial asthma and allergic rhinitis. However, it cannot stop the attack of bronchial asthma already in progress but prevents the 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 adults, take 2 tablets (225 mg of the active ingredient) at a time, twice a day after breakfast and dinner. The dosage may be adjusted according to your age and symptoms. Strictly follow the instructions.
- If you miss a dose and it is 5 hours or more before the next dose, take a missed dose as soon as possible. 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 nausea, diarrhea, abdominal pain, gastric discomfort, headache, drowsiness, dizziness, rash, itch, hives and erythema exsudativum multiforme. 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.

- ·reduction in blood pressure, consciousness disorder, respiratory distress [shock, anaphylactoid symptoms]
- •bleeding tendency including purpura, nose bleeding and gum bleeding [decreased platelets]
- •general malaise, loss of appetite, yellowing of the skin and the mucosa [hepatic dysfunction]
- ·fever, dry cough, respiratory distress [leukopenia, interstitial pneumonia, eosinophilic pneumonia]
- muscular pain, lassitude, reddish brown urine [rhabdomyolysis]

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 direct sunlight, heat and moisture.
- •Discard the remainder. Do not store them.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.