

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

Internal

Revised: 04/2016

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: ONON capsules 112.5mg**

**Active ingredient:** Pranlukast hydrate

**Dosage form:** white to yellowish white opaque capsule, major axis: 16 mm, minor axis: 5.7 mm

**Imprint or print on wrapping:** (face) オノン 112.5mg, ONO678, (back) ONON112.5mg, オノン 112.5mg, 気管支喘息・アレルギー性鼻炎治療剤, 湿気注意



**Effects of this medicine**

This medicine selectively binds to leukotriene receptor and antagonizes its action. It consequently suppresses increase in airway contraction, vascular permeability, mucosal edema and hypersensitivity to improve symptoms associated with bronchial asthma or allergic rhinitis.

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.

**The following patients may need to be careful when 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 or foods.
- 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 capsules (225 mg of the active ingredient) at a time, twice a day after breakfast and supper. The dosage may be adjusted according to the disease, age and symptoms. 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 follow your 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 nausea, diarrhea, abdominal pain, gastric discomfort, headache, dizziness, rash, itching, hives, erythema exsudativum multiforme, pain in limbs, enlargement of the breasts, breast induration, breast pain and gynecomastia. 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.**

- respiratory distress, cold sweat, shortness of breath [shock, anaphylaxis]
- nasal bleeding, gum bleeding, subcutaneous bleeding in limbs [thrombocytopenia]
- general malaise, loss of appetite, yellowing of the skin and the conjunctiva [hepatic dysfunction]
- fever, dry cough, chest pain [leukopenia, interstitial pneumonia, eosinophilic pneumonia]
- muscular pain/rigidity in limbs, general malaise [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** / /

For further information, talk to your doctor or pharmacist.