

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:Fexofenadine Hydrochloride Tablets 60mg "SANIK"

Active ingredient:Fexofenadine hydrochloride

Dosage form:light orange tablet, major axis: 12.1 mm, minor axis: 5.6 mm, thickness: 4.1 mm

Imprint or print on wrapping:フェキソフェナジン塩酸塩錠 60mg「SANIK」、フェキソフェナジン,60mg,n02 60,Fexofenadine hydrochloride 60mg 「SANIK」、アレルギー性疾患治療剤,フェキソフェナジン「SANIK」60mg



Effects of this medicine

This medicine has antagonistic action on histamine H₁ receptors and suppressive action on releasing of various chemical mediators.

It is usually used to treat allergic rhinitis or hives, and itch associated with skin diseases (eczema, dermatitis, cutaneous pruritus and atopic dermatitis).

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 and children aged 12 years or older, take 1 tablet (60 mg of the active ingredient) at a time, twice a day. For children aged between 7 to 11 years, take 30 mg of the active ingredient at a time, twice a day. The dosage may be adjusted according to disease and symptoms of the patient. This preparation contains 60 mg in a tablet. 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 headache, sleepiness, nausea, rash, angioedema, itch, hives and flushing. 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, fall in blood pressure, loss of consciousness, angioedema, chest pain, flushing [shock, anaphylaxis]
- general malaise, loss of appetite, yellowing of the skin and the whites of the eyes [liver dysfunction, jaundice]
- fever, sore throat [agranulocytosis, leucopenia, neutropenia]

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.