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

Internal

Revised: 11/2015

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: Allegra tablets 60mg

Active ingredient:Fexofenadine hydrochloride

Dosage form: pale orange tablet, major axis: 12.1 mm, minor axis: 5.6 mm

Print on wrapping:アレグラ 60, Allegra 60

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 in the treatment of symptoms of allergic rhinitis and hives, and itching of skin associated with skin diseases (eczema, dermatitis, pruritus and atopic dermatitis).

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 and children aged 12 years and older, take 60 mg of the active ingredient at a time, twice daily. For children aged 7 to 11 years, take 30 mg of the active ingredient at a time, twice daily. The dosage may be adjusted according to the disease or symptoms. This preparation contains 60 mg of the active ingredient 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, aggravation of asthma, abdominal pain, dizziness, lassitude, gastroenteritis, 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.

- •breathing difficulty, blood pressure decreased, loss of consciousness, angioedema, chest pain, flushing [shock, anaphylaxis]
- •general malaise, loss of appetite, yellowing in skin and white of eyes [hepatic dysfunction, jaundice]
- •fever, throat pain [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.

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For further information, talk to your doctor or pharmacist.