

# 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:**FEXOFENADINE HYDROCHLORIDE TABLETS 60mg "CEO"

**Active ingredient:**Fexofenadine hydrochloride

**Dosage form:**light orange tablet, diameter: 8.6 mm, thickness: 4.2 mm

**Print on wrapping:**(face) フェキソフェナジン塩酸塩錠 60mg「CEO」, CEO102, 60mg  
(back) FEXOFENADINE60mg, フェキソフェナジン, 60mg



## Effects of this medicine

This medicine has antagonistic action on histamine H<sub>1</sub> receptors and suppressive action on releasing of various chemical mediators to inhibit action of allergenic substances. It improves seasonal allergic rhinitis such as cedar pollen allergy, nasal symptoms of year-round allergic rhinitis (sneeze/nasal discharge/nasal congestion) caused by mite or house dust, and various skin itch.

It is usually used to treat symptoms of allergic rhinitis and hives, and skin itch 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, take 1 tablet (60 mg of the active ingredient) at a time, twice a day. For children aged 7 to 11 years, take 30 mg of the active ingredient at a time, twice a day. For children aged 12 years and older, take 1 tablet (60 mg) at a time, twice a day. The dosage may be adjusted according to your disease and symptoms. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue 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, drowsiness, nausea, rash, angioedema (swelling of eyelid/lip), itch, hives, flush, abdominal pain, dizziness and dullness. 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, reduction in blood pressure, loss of consciousness, angioedema, chest pain, flush [shock, anaphylaxis]
- general malaise, loss of appetite, yellowing of the skin and the whites of 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.