

# 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:** Dellegra combination tablets

**Active ingredient:** Fexofenadine hydrochloride  
Pseudoephedrine hydrochloride

**Dosage form:** pale orange tablet, diameter: 17.5 mm, minor axis: 7.8 mm

**Print on wrapping:**



## Effects of this medicine

Fexofenadine hydrochloride has antagonistic action on H<sub>1</sub> receptors and suppressive action on releasing of various chemical mediators. Pseudoephedrine hydrochloride decreases blood flow of nasal mucosa and shows effective improvement on nasal congestion. It improves symptoms of sneezing, runny nose and nasal congestion associated with seasonal allergic rhinitis such as cedar pollinosis, and perennial allergic rhinitis caused by mite and house dust. It is usually used in the treatment of allergic rhinitis.

## 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 have: hypertension, coronary artery disease, angle closure glaucoma or urinary retention.  
If you have a history of insomnia, dizziness, weakness, tremor or arrhythmia induced by sympathomimetic medicines.
- 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.)
- 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 2 tablets at a time, twice daily, in the morning and evening, on an empty stomach. Strictly follow the instructions.
- Never chew or crush the tablet since this medicine contains controlled-release layer. Swallow with water as it is.
- Because this controlled-release layer is hard to melt, it may be excreted in the feces as a tablet after active ingredient release.
- If you miss a dose, take a dose as soon as you remember. 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, rash, fatigue, dry mouth, angioedema, itching, 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, hives, flushing [shock, anaphylaxis]
- paroxysmal muscle contraction [convulsion]
- general malaise, loss of appetite, yellowing in skin and white of eyes [hepatic dysfunction, jaundice]
- throat pain, headache, muscle pain [agranulocytosis, leucopenia, neutropenia]
- fever, erythema, many small pustule [acute generalized exanthematous pustulosis]

**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.