

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

External

Revised: 12/2022

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:Zaditen Ophthalmic Solution 0.05%

Active ingredient:Ketotifen fumarate

Dosage form:colorless to slightly yellow ophthalmic solution (plastic bottle) 5mL(cap)

green

Imprint or print on wrapping:



Effects of this medicine

This medicine improves symptoms like eye itching and hyperemia by inhibiting production or release of allergic substances (histamine, etc.).

It is usually used to treat allergic conjunctivitis.

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 wear contact lenses.
- 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, apply 1 to 2 drops at a time, 4 times a day (in the morning, afternoon, evening, and before bedtime).
Strictly follow the instructions.
- Before applying eye-drops, wash your hands thoroughly. Take care not to touch the dropper tip against the eye when applying. After dropping the solution into your eyes, keep your eyes closed for 1 to 5 minutes pressing your inner corner of the eyes lightly. Wipe off any excess liquid with a clean tissue.
- If you need to use other eye drops at the same time, take more than 5 minutes intervals between medicines.
- If you are wearing soft contact lenses, take off the lenses and then apply the medicine. Wait more than 15 minutes to wear contact lenses again.
- If you miss a dose, apply 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 not use two doses at one time.
- If you accidentally use more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop using 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 eye stimulation, itching, blepharitis (eyelids are itchy) and sleepiness. 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.

No pertinent entries.

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. Store at room temperature (1 to 30 degrees Celsius) in an accompanying bag.
- Discard the remainder. Do not store them. If you do not know how to discard them, please consult the pharmacy or medical institution where you received them. Do not give them to others.
- Do not use any medicine that has been stored for more than 4 weeks after opening.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.