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

External

Revised: 09/2024

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: KETOTIFEN OPHTHALMIC SOLUTION 0.05% "SW"

Active ingredient: Ketotifen fumarate

Dosage form: colorless to slightly yellow, limpid ophthalmic solution, 5mL, (cap) light



Imprint or print on wrapping:

Effects of this medicine

This medicine suppresses actions of allergenic substance (histamine) or inflammatory substances and improves allergic symptoms.

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.
- Make sure not to let the tip of the container touch any part of your eye.
- After applying, keep your eyes closed without blinking for a while (1 to 5 minutes).
- •If this medicine gets on your eyelid, wipe it off immediately.
- •If you need to apply other eye drops at the same time, wait more than 5 minutes.
- 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 the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and follow your regular dosing schedule. You should not apply two doses at one time.
- · If you accidentally apply more than your prescribed dose, consult with your doctor or pharmacist.
- •Do not stop applying 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 blepharitis, eyelid dermatitis, itching, conjunctival hyperemia, stinging eyes 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.
- •Discard the remainder that has passed 1 month after opening without storing it. If you do not know how to dispose of it, please consult the pharmacy or medical institution where you received it. Do not give it to others.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.