

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

External

Revised: 03/2025

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:FLUOROMETHOLONE ophthalmic solution
0.1%“WAKAMOTO”

Active ingredient:Fluorometholone

Dosage form:white or milky white ophthalmic suspension, 5mL, (cap) deep pink

Imprint or print on wrapping:



Effects of this medicine

This medicine is a synthetic adrenocortical hormone (steroid) preparation and suppresses eye inflammation by anti-inflammatory and anti-allergic effect.

It is usually used to treat eye inflammatory disease such as blepharitis, conjunctivitis, keratitis, and iritis.

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 have: corneal epithelial abrasion, corneal ulcer, viral conjunctival/corneal disease, or tuberculous/fungal/suppurative eye disease.
- 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, shake the bottle well, and apply 1 to 2 drops at a time, 2 to 4 times a day. The dosage may be adjusted according to your age or symptoms. Strictly follow the instructions.
- If you are a child patient (especially less than 2 years old), you should especially follow your doctor's instructions.
- Make sure not to let the tip of the container touch any part of your eye.
- After applying, do not blink and keep your eyes closed for a while (1 to 5 min).
- If the medicine gets on your eyelid, wipe it off immediately.
- If you use this medicine concomitantly with other eye drops, wait more than 5 minutes.
- If you miss a dose, apply the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and continue 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 stinging eyes, conjunctival hyperemia, corneal deposits, blepharitis, eyelid dermatitis, rash and delayed healing of wound. 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.

- (continued use) eye pain, headache, focus disorder [glaucoma]
- eye pain, lacrimation, focus disorder [corneal herpes, keratomycosis, pseudomonas aeruginosa infection, corneal perforation]
- (long-term use) focus disorder [posterior subcapsular cataract]

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.
- Keep the container upward as it may be difficult to disperse the particles after shaking depending if you put it incorrect.
- 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.