

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

External

Revised: 02/2014

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: PREDONINE Ophthalmic Ointment

Active ingredient: Prednisolone acetate

Dosage form: white to pale yellowish-white ophthalmic ointment

Imprint or print on wrapping:



Effects of this medicine

This medicine is a synthetic corticosteroid, and it improves the symptoms such as itch and redness by inflammation in eyes.

It is usually used for the treatment of ophthalmic inflammatory disorders such as blepharitis, conjunctivitis, keratitis, etc.

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 are a patient with corneal epithelial abrasion, corneal ulcer, viral conjunctival disease, viral corneal disease, tuberculous eye disease, fungal eye disease or suppurative eye disease.
- 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 a suitable amount of the medicine to affected parts, several times a day. The dosage may be adjusted according to your disease and symptoms. Strictly follow the instructions.
- Before using, wash your hands thoroughly.
Pull down your lower eyelid with forefinger. Squeeze the tube and apply the medicine to the inside of your eyelid sideways, long and thinly, and then close your eye, and press your eyelid lightly. However, do not press and rub it too strongly.
If the medicine overflows outside of your eye, wipe off it with clean gauze or tissue paper, etc.
- When using the medicine, make sure that the tube tip does not touch your eye or eyelashes, because a touch may cause pollution.
Wipe the tube tip with clean gauze, tissue paper, etc. so as not to pollute the medicine, and close the cap firmly after use.
- If you miss a dose, use it as soon as you remember. If it is close to your next dose, skip the missed dose.
- If you accidentally use more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop using the 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 feeling of stimulation. 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) nausea, pain in the eyes, failing eyesight, headache [glaucoma]
- sensitive to light, teary eyes, irritation in the eyes [induction of corneal herpes, keratomycosis, pseudomonas aeruginosa infection]
- (When using for herpes corneae, corneal ulcer, injury, etc.) foggy vision, teary eyes, sensitive to light [perforation]
- (long-term use) foggy vision, sensitive to light, failing eyesight [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 the medicine out of the reach of infants and children. Store it at room temperature (1 to 30 degrees Celsius) away from direct sunlight and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.