

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

External

Revised: 07/2011

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:RINDERON Ophthalmic, Otic and Nasal Solution 0.1%

Active ingredient:Betamethasone sodium phosphate

Dosage form:clear colorless, ophthalmic, otic and nasal solution

Imprint or print on wrapping:



Effects of this medicine

This medicine is a synthetic adrenocortical hormone agent (steroid) and it improves the symptoms such as itch, redness and swelling by inflammation in eyes, ears and nose.

It is usually used for the treatment of inflammatory diseases such as blepharitis, conjunctivitis in the ophthalmologic field. It is usually used for the treatment of inflammatory and/or allergic diseases such as external otitis, tympanitis and allergic rhinitis in the otological field.

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, conjunctival or corneal disease caused by viruses, tuberculous eye disease, fungal eye disease, suppurative eye disease, tuberculous or viral disease in ear or nose.
- 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))
- For ophthalmic treatment: In general, apply 1 or 2 drops at a time, 3 or 4 times a day by ophthalmic administration.
For otic and nasal treatments: In general, apply the suitable amount once to several times a day, by ear dripping, nasal dripping, ear instillation, usage of a nebulizer or tampons, or pouring into affected parts.
In any of these cases, the dosage may be adjusted according to your disease and symptoms. Strictly follow the instructions.
- Before using, wash your hands thoroughly.
For ophthalmic drop: Turn your face up, and pull down your lower eyelid with your forefinger, and apply the medicine to the affected eye. After dropping the solution into the eye, keep the eye closed for 1 to 2 minutes without blinking. If more than two kinds of medicines are used, apply to the eye after an interval of at least 2 to 3 minutes, preferably 5 minutes or more.
For ear dripping: Turn the affected ear upward, and apply the medicine to the ear. Usually keep that position for 2 to 3 minutes.
For nasal dripping: Turn the affected nose upward, and apply the medicine to the nose. Usually keep that position for 2 to 3 minutes.
Wipe off any excess liquid with a clean gauze or tissue paper.
- When applying the medicine, make sure that the dropper tip does not touch your eyes, ears or nose, because it may cause pollution.
- Close the cap firmly so as not to pollute the medicine 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 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 stimulating feeling etc. 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 or 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 degree Celsius), away from light and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.