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

External

Revised: 08/2020

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:LINOLOSAL OPHTHALMOLOGIC-OTORHINOLOGIC SOLUTION 0.1%

**Active ingredient:**Betamethasone sodium phosphate

**Dosage form:**limpid and colorless, ophthalmic, otic and nasal solution, (cap) red-purple

Print on wrapping:

#### Effects of this medicine

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

It is usually used to treat inflammatory disease such as blepharitis, conjunctivitis in the ophthalmological field or inflammatory / allergic disease such as otitis externa, otitis media or allergic rhinitis in the otorhinological field.

#### Before 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.

If you have: corneal epithelial abrasion...mycotic eye disease, suppurative eye disease, tubercular or viral disease in the ear or nose, diabetes mellitus.

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))
- For ophthalmic treatment: In general, apply 1 or 2 drops at a time, 3 or 4 times a day.
- <u>For otic and nasal treatments</u>: In general, apply a suitable amount once to several times a day, by ear dripping, nasal dripping, ear instillation, usage of nebulizer or tampons, or pouring into the affected parts.
- In any of these cases, the dosage may be adjusted according to your disease, age and symptoms. Strictly follow the instructions.
- For ophthalmic drop: If more than two kinds of medicines are used, apply to the eye after an interval of 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.
- •Make sure not to let the dropper tip touch any part of your eyes, ears or nose.
- ·Wipe off any excess liquid immediately.
- •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 take 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 stimulating feeling. 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, failing eyesight [glaucoma]
- •eye pain, teary eyes, failing eyesight [induction of corneal herpes, keratomycosis, pseudomonas aeruginosa infection]
- •(when used for corneal herpes, corneal ulcer or injury) 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 out of the reach of children. Store away from light, heat and moisture. Store in the accompanying bag.
- •Discard the remainder if 1 month have passed after opening. Do not store them.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.