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

External

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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 0.02%"WAKAMOTO"

Active ingredient:Fluorometholone

Dosage form: white or milky white ophthalmic suspension, (cap) pale pink

Print on wrapping:

Effects of this medicine

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

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

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, corneal ulcer.

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.
- •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 never 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, rash, eye irritation and conjunctival hyperemia. 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. Put this medicine in the accompanying bag and store away from direct sunlight, heat.
- •Keep the container upward as it may be difficult to disperse the particles after shaking depending if you put it incorrect.
- •Discard the remainder after 1 month after opening. Do not store them.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.