

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:FLUCORT Ointment 0.025%

Active ingredient:Fluocinolone acetonide

Dosage form:white to faint yellow ointment

Imprint or print on wrapping:フルコート軟膏 0.025%



Effects of this medicine

This medicine is a synthetic adrenocortical hormone agent that has anti-inflammatory effects, and thus improves symptoms such as redness, swelling, itches in the skin.

It is usually used for the treatment of eczema/dermatitis syndrome, pruritus cutaneous, prurigo syndrome, insect bites, psoriasis, palmoplantar pustulosis, drug eruption/toxicoderma.

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 skin infection with bacteria/fungus/spirochete bacterium/virus, skin disease caused by insects (ticks, hair lice, etc.), eczematous external otitis with eardrum perforation, skin ulcer, heat burn/frostbite.
- 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 the affected area, once to several times a day. The dosage may be adjusted according to your disease and symptoms. Strictly follow the instructions.
- Do not apply this medicine into your eyes because it is not for ophthalmic use.
- When applying to the diaper area, pay close attention and follow the instructions of your doctor or pharmacist.
- If you miss a dose, apply it as soon as possible. However, if it is almost time for the 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

- Do not apply this medicine as a makeup base or after shave.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include skin irritation, aggravation of symptoms, skin infection, acneiform eruption, rosacea-like dermatitis/perioral dermatitis (facial erythema, etc.), steroid-induced dermatosis (skin atrophy, etc.), rash, contact dermatitis and erythema. 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.

- (When applying the medicine to your eyelids) see a ring around bright light, foggy vision, sensitive to light [ocular hypertension]
- (When applying the medicine to your eyelids, or when using a large amount of it or using it for long term) eye pain, headache, failing eyesight [glaucoma]
- (When using a large amount of the medicine or using it for long term) 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 direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.