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: MYSER Cream 0.05%

Active ingredient:Difluprednate Dosage form:white cream

Imprint or print on wrapping:マイザークリーム 0.05 %

マイザークリーム0.05% 10g [

Effects of this medicine

This medicine is a synthetic adrenocortical hormonal agent (steroid) that has anti-inflammatory and antiallergic effects, and thus reduces symptoms such as redness, swelling and itch.

It is usually used to treat eczema/dermatitis, prurigo, insect sting, psoriasis, palmoplanter pustulosis, drug eruption/toxicoderma, 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 have: skin infections, eczematous external otitis, 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 to your eyes because this cream is not for ophthalmological use.
- ·Avoid using tight-fitting diapers or plastic pants if the medicine is being used on your diaper area.
- ·If you miss a dose, apply a dose as soon as possible. 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 folliculitis/furuncle, acneiform eruption, steroid flush/capillary dilatation, skin atrophy, erythema and contact dermatitis. 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.

- •seeing a rainbow-like ring of colors, blurred vision (foggy vision), sensitive to light [ocular hypertension when applying the medicine to the eyelid skin]
- •eye pain, headache, decreased vision [glaucoma when applying the medicine to the eyelid skin in large doses and/or over a long time]
- •foggy vision, sensitive to light, and/or decreased vision [posterior subcapsular cataracts when applying the medicine in large doses and/or over a long time]

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.