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

External

Revised: 03/2014

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: RINDERON-DP Cream

Active ingredient: Betamethasone dipropionate

Dosage form:white cream Imprint or print on wrapping:

Effects of this medicine

This medicine is a synthetic corticosteroid, and it improves the symptoms such as itch, redness and swelling by inflammation in skin.

It is usually used for the treatment of eczema, dermatitis, psoriasis, etc. As a general rule, it should not be used for inflammation caused by infections with bacteria, fungi, etc. Furthermore, it should not be used for skin ulcers, serious burns or frostbites, because the medicine may delay the healing process.

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 skin infections by bacteria, fungi, etc., skin diseases caused by animals such as mite and crab lice, abnormalities of the eardrum, skin ulcers, burns or frostbites.
- · 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
- to be written by a healthcare professional))
- •In general, apply a suitable amount of the medicine to affected parts, once to several times a day. The dosage may be adjusted according to your disease and symptoms. Strictly follow the instructions.
- Take care so that the medicine does not get into your eyes.
- •Never apply the medicine for cosmetic purposes, under a makeup, after a shave, etc.
- •Pay special attention when applying the medicine to where a diaper touches, and follow the instructions for 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 the 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 folliculitis (suppuration of pores), furuncle (boil), skin infection, steroid acne, skin atrophy 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, or when using a large amount of it or using it for extended period over a wide area) headache, foggy vision, pain in the eyes, sensitive to light [ocular hypertension, glaucoma, 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 degrees Celsius) away from light and moisture.
- •Discard the remainder. Do not store them. For disposal methods, consult the pharmacy or the medical institution from which you have received the medicine.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.