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

External Revised: 04/2023

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: Kindavate Ointment 0.05%

Active ingredient:Clobetasone butyrate

Dosage form:white translucent ointment

Imprint or print on wrapping:キンダベート軟膏 0.05%

Effects of this medicine

This medicine is a steroid preparation for external use that improves symptoms such as redness, swelling and itch through anti-inflammatory or anti-allergic actions.

It is usually used to treat atopic dermatitis, or eczema/dermatitis on the face, neck, armpit or in the genital area.

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 eczematous external otitis with eardrum perforation, skin ulcer, burn/frostbite or skin infections due to bacteria, fungi, virus, etc.
- · 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 an appropriate amount of this medicine to the affected area, once to several times a day. The dosage may be adjusted according to symptoms. Strictly follow the instructions.
- •Pay attention so that this medicine does not get in your eyes.
- •Do not use this medicine under makeup or after shaving, as adverse drug reactions may occur.
- •Avoid using tight-fitting diapers or plastic pants if this medicine is applied to an area touching the diaper.
- 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.
- 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. If your symptoms do not improve or worsen after using this medicine correctly as instructed, consult with your doctor or pharmacist.

Precautions while taking this medicine

• Avoid let this medicine get on contraceptive latex products, such as condoms, since the oleaginous ingredients used for the base of this medicine may degrade or damage contraceptive products made of latex rubber.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include itch, folliculitis, transient irritating sensation and steroid acne. 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.

·headache, foggy vision, eye pain [ocular hypertension, glaucoma, posterior capsule 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

- Tighten the cap of the tube after use. Keep out of reach of children. Store away from direct sunlight, heat and moisture.
- •Discard the remainder. Do not store them. If you do not know how to discard, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

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For further information, talk to your doctor or pharmacist.