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

External

Revised: 01/2021

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: ANTEBATE OINTMENT 0.05%

Active ingredient:Betamethasone butyrate propionate

Dosage form: white ointment

Imprint or print on wrapping:アンテベート軟膏 0.05%, TO-1860

Effects of this medicine

This medicine is a steroid for external use, and suppresses skin inflammation and improves symptoms such as redness, swelling and itch.

It is usually used to treat eczema, dermatitis, and psoriasis.

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 infections due to bacteria/fungi, ulcer and 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 an appropriate amount of the medicine to the affected area, once to several times a day. Strictly follow the instructions.
- ·Pay extra attention when you apply this medicine to areas that touch the diaper. Follow the instructions.
- •Do not apply this medicine to your eyes (cornea and conjunctiva). If the medicine accidentally gets into your eyes, rinse it off with water. (If you still feel something wrong, consult with your doctor or pharmacist.)
- •If you miss a dose, apply the missed dose when you remember. However, if it is almost time for the next dose, skip the missed dose and then apply the next dose as instructed. You should not 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

- If you use this medicine for a long period of time, consult with your doctor regularly.
- •Do not use this medicine as a makeup base or after shaving.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include skin fungal infection (candidiasis, tinea, etc.), bacterial infection (contagious impetigo, folliculitis, etc.), acne, steroid skin (skin atrophy, small visible spider-like veins, flushing, etc.), stimulating feeling and eczema. If any of these symptoms occurs, 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 you use this medicine in a large dose or over a long period of time over a large area around the eyes, such as the eyelids) eye pain, sensitive to light, foggy vision, headache [ocular hypertension, glaucoma, 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 and moisture. Store at room temperature (1 to 30 degrees Celsius).
- •Discard the remainder. Do not store them. Consult with your pharmacy or medical institution on how to discard them.

_			
-or	healthcare	professional	I IISA ANIV

/ /

For further information, talk to your doctor or pharmacist.