

# 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:**BETNEVATE N Ointment

**Active ingredient:**Betamethasone valerate  
Fradiomycin sulfate

**Dosage form:**white semi-translucent ointment

**Imprint or print on wrapping:**ベトネベートN軟膏



## Effects of this medicine

This medicine is a combination preparation of synthetic adrenal corticosteroid and antibiotics, and suppresses skin inflammations by its local anti-inflammatory effect to improve swelling and itch. It shows effect on secondary infections and suppurative skin diseases by its antibacterial action.

It is usually used to treat deep skin infection, chronic pyoderma, eczema/dermatitis (including keratoderma tylodes palmaris progressiva, lichen Vidal, radiodermatitis, and solar dermatitis), psoriasis, insect bites or prurigo (including urticaria perstans) accompanied by moistness/erosion/eschar or with secondary infections, secondary infections in external injury/thermal burn or surgical wound or for the management after otorhinolaryngological surgery.

## 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, eardrum perforation, skin ulcer or thermal burn/frostbite classified as second degree or higher.
- 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 or rub appropriate amount of this medicine directly to the affected area; or spread the medicine on sterilized gauze and apply it to the affected area; once to several times a day. The dosage may be adjusted according to the symptoms.
- Since the adverse effects are more likely to occur if you apply this medicine in a large amount or for a long term on large areas, or with occlusive dressing technique (ODT), strictly follow the instructions. Pay extra attention to the fact that use of diapers causes same effect as ODT.
- Do not use this medicine for ophthalmic application.
- If you miss a dose, apply the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and follow 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.

## Precautions while taking this medicine

- This medicine should be used only for therapeutic purposes. Do not use it as makeup base or after shaving.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include skin infections (contagious impetigo, folliculitis, etc.), skin fungal infections (tinea, candidiasis, etc.), viral infections, skin irritation, contact dermatitis and rash. 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 circle of lights when you look at bright light, sensitive to bright light, headache, eye pain, reduced visual acuity [increased intraocular pressure, 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 out of the reach of children. Store at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard, seek advice of your dispensing pharmacy or medical institution. Do not give the unused medicines to others.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.