

# 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:**BESELNA Cream 5% [for condyloma acuminatum]

**Active ingredient:**Imiquimod

**Dosage form:**white to slightly yellow cream

**Imprint or print on wrapping:**(divided aluminum package)ベセルナクリーム 5%, 250mg,  
MO 651



## Effects of this medicine

This medicine suppresses viral replication which causes condyloma acuminatum and enhances immunocompetence to damage the cells infected by the viruses.

It is usually used in the treatment of condyloma acuminatum (limited to the external genitalia and around the anus).

## 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 the wart is in the urethra, vagina, uterine cervix, rectum, anus, or in other area except the external genitalia and around the anus.
- 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 appropriate amount of the medicine to the affected area once a day, 3 times a week (e.g. on Monday, Wednesday and Friday, or on Tuesday, Thursday and Saturday to avoid continuous use of it), before going to bed. After applying, leave the application site as it is, and wash the applied medicine off with soap and water or warm water when you get up the next morning (6 to 10 hours after applying it). Strictly follow the instructions.
- The medicine should not be used longer than 16 weeks in principal.
- Apply the medicine thinly to the wart only, then rub until it becomes invisible.
- Do not apply the medicine to wart with wound or a wound around the wart.
- Do not seal the application site with a bandaid or tape.
- If you miss a dose, apply a dose before going to bed the next night that you missed the application. Do not apply two days in a row after that.
- If you accidentally apply more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop applying the medicine unless your doctor instructs you to do so.

## Precautions while taking this medicine

- Strictly follow the dosage regimen as instructed by your doctor or pharmacist because severe redness, skin sore, ulcer or epidermal desquamation may occur in the application site or its surroundings.
- In the process of healing, redness, skin sore, epidermal desquamation or swelling may occur in the application site or its surroundings. If these symptoms develop heavily, wash the medicine off with soap and water or warm water, then contact with your doctor or pharmacist promptly.
- Flulike symptoms such as chilliness, fever or muscular pain may occur. If these symptoms develop, contact with your doctor or pharmacist promptly.
- The skin may become discolored or depigmented after using the medicine, and never return in some cases.
- In women, if the medicine is applied near the vaginal opening or urethral opening, pain or swelling may occur near the urethral opening or its surroundings and may cause urination difficulties. If you need to apply the medicine near the vaginal opening or urethral opening, apply the medicine carefully on the affected area only.
- In men with pseudophimosis and is in need to treat a wart on the inner surface of the prepuce, redness, skin sore, epidermal desquamation or swelling in the skin may occur easily. Wash the affected area by reversing the foreskin everyday and keep the inner surface of the prepuce clean.
- Oil and fat contained in the medicine will cause quality deterioration and may cause damage to contraceptive latex products such as condoms. Pay attention not to let the medicine attach to any contraceptive latex products.
- Skin problems may appear to your sex partner. Avoid sexual behavior with the medicine being applied on your body.
- If the application site is exposed to the sunlight, photosensitivity reaction (rash, blister, excessive sunburn, pigmentation or itch) may occur. Wash off the medicine left on your fingers or accidentally attached to the areas

other than wart (face etc.) with soap and water or warm water after applying the medicine.

**Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include erythema, erosion, epidermal desquamation, edema, pain and eczema on the application site. 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.**

- severe ulcer, skin sore, redness, swelling or epidermal desquamation on the application site [skin disorders including serious ulcer, erosion, erythema, edema, epidermal desquamation]
- difficulty in urination caused by pain and edema in the urethral opening or its surroundings (in women) [dysuria]

**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 below 25 degrees Celsius and away from direct sunlight and moisture. Avoid freezing.
- Discard the remainder. Do not store them.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.