# 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: MOIZERTO ointment 0.3%**

Active ingredient: Difamilast Dosage form: white ointment Imprint or print on wrapping:



#### Effects of this medicine

This medicine suppresses skin inflammation and improves the symptoms of atopic dermatitis by inhibiting the activity of phosphodiesterase 4 (PDE4) and regulating the expression of substances involved in inflammatory and anti-inflammatory response in cells.

It is usually used to treat atopic dermatitis.

# 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 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, for children, apply an appropriate amount of this medicine to the affected area twice a day. Strictly follow the instructions.
- •2.5 cm of ointment (from the tip of an adult forefinger to its first joint) squeezed out from the tube is the amount necessary for two palms-size eruption of an adult.
- •Wash your hands thoroughly before applying the ointment to the affected area and your fingers clean right after finished.
- •Apply this medicine by avoiding the infected skin area.
- •Do not apply this medicine to mucosa, ulcer or erosion clearly forming plaque.
- •When applying around eyes, pay attention not to let the medicine get into the eyes. (If it gets into your eyes, wash out with water immediately. When stimulating sensation persists after washing out, consult with the medical institution.)
- •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 continue your regular dosing schedule. You should not apply two doses at one time.
- · 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

• Female patients with a possibility of pregnancy should avoid pregnancy while using this medicine and for a certain period of time after its completion.

#### Possible adverse reactions to this medicine

The most commonly reported adverse reactions include pigmentation disorder, folliculitis (furuncle) and pruritus (itching). 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.

No pertinent entries.

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 firmly each time you use the medicine. Keep out of the reach of children. Store away from direct sunlight, heat and moisture.
- •Discard the remainder. Do not store them.

#### For healthcare professional use only

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