

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

External

Revised: 06/2023

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:Protopic Ointment 0.03% for pediatric use

Active ingredient:Tacrolimus hydrate

Dosage form:white to faint yellow ointment

Imprint or print on wrapping:プロトピック軟膏 0.03%小児用, 5g



Effects of this medicine

This medicine suppresses the body's excessive immune response, thus improves symptoms of atopic dermatitis. It is usually used to treat atopic dermatitis in children (aged 2 to 15 years old).

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 the following symptoms on your skin: ulcerated or erosive (sores) skin, ichthyosiform erythroderma (a condition of scale-like, flakey or reddened skin), impetigo contagious, herpes simplex, boils or acne.
- If you have kidney impairment or hyperkalaemia.
- If you are younger than 2 years old.
- If you are undergoing ultraviolet treatment.
- 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 this medicine on the affected area, once or twice a day. The amount depends on age, body weight and the area of your symptoms. The standard maximum single dose is 1 g for 2 to 5 years old (less than 20 kg), 2 g to 4 g for 6 to 12 years old (20 kg to 50 kg), and 5 g for 13 years old or older (50 kg or more), but it may be reduced according to the age appropriately. Strictly follow the instructions.
- Wash your hands before and after applying the medicine.
- Do not apply the medicine on other surfaces than skin such as the mucosa of the mouth, nose, etc. or on the vulva.
- Pay close attention not to let the medicine get into your eyes. If the medicine gets into your eyes, wash it away with water. If irritation persists after washing, consult with an ophthalmologist.
- If you miss a dose, apply one dose when you remember, but the next dose should be at least 12 hours apart. You should never use two doses at one time.
- If you accidentally apply more than your prescribed dose, wipe it off immediately. If you apply more than the amount prescribed dose at one time, consult with your doctor or pharmacist.
- Do not stop using this medicine unless your doctor instructs you to do so. If improvement was not observed after two weeks of continuous use, consult with your doctor or pharmacist.

Precautions while taking this medicine

- Prevent the applied area from being exposed to sunlight for a long time. Avoid using tanning or ultraviolet lamps.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include pain (tingling feeling, smarting feeling), feeling hot (burning sensation, feeling of hot flushes), itching, skin infections (inflammation of pores, impetigo contagious, water warts, herpes simplex, tinea of the crotch, athlete's foot, etc), boils such as acne, sore throat and lymphadenitis. 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

- Keep out of the reach of infants and children. Store away from direct sunlight, heat and humidity.
- Discard the remainder. Do not store it. Consult with your dispensing pharmacy or medical institution when you do not know how to discard of it. Do not give it to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.