

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

External

Revised: 09/2007

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:Urepearl Cream 10%

Active ingredient:Urea

Dosage form:emulsified white ointment (cream) with a slightly characteristic odor (20 g or 50 g in tubes, 500 g in bottles)

Imprint or print on wrapping:



Effects of this medicine

This medicine prevents dryness of skin caused by keratosis and softens keratin by water-retaining effect.

It is usually used for the treatment of atopic dermatitis, progressive keratoderma of the fingers and palms (dry eczema), senile xeroderma, palmoplantar keratoderma, plantar dermatitis with fissure formation, lichen pilaris follicularis, and ichthyosis.

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 inflammation or wounds on the skin.
- If your skin is sensitive to skin irritation.
- 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 this medicine (cream) to the affected area and then gently rub it into the skin with the fingertips two or three times daily after cleansing of the skin. The dose should be adjusted according to your symptoms. Strictly follow the instructions.
- Do not apply the cream to mucous membranes such as ocular mucous membrane. Do not apply the cream directly to ulcerated, erosive or wounded skin area.
- If you miss a dose, apply the missed dose as soon as you remember. You should not apply two doses at the same 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include pain, sensation of heat, flushing, pruritus, eczematization, fissure and hypersensitivity symptoms. 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 children. Store away from direct sunlight, heat and moisture.
- If there is any remainder of the medicine after use, discard the remainder. Do not store it.
- Stainless steel utensils such as spatula will corrode if placed in contact with this cream for a prolonged period.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.