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

External

Revised: 10/2018

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: PROSTANDIN OINTMENT 0.003%**

Active ingredient: Alprostadil alfadex

Dosage form: white to white translucent ointment

# Imprint or print on wrapping:プロスタンディン軟膏 0.003% 10g、30g Effects of this medicine

This medicine improves blood flow at areas with pressure ulcer (bedsore) or ulcer and promotes granulation and epidermal regeneration.

It is usually used to treat pressure ulcer and skin ulcer (burn ulcer, diabetic ulcer, leg ulcer, postoperative ulcer).

## 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 heart failure or bleeding (intracranial bleeding, hemorrhagic eye disease, digestive bleeding, hemoptysis).
- •If you are pregnant, possibly 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 an appropriate amount of this ointment, depending on your symptoms or the size of the affected area. After disinfecting/cleansing the area /ulcer, spread an appropriate amount of this ointment on a gauze and apply to the affected area, or apply the ointment directly to the affected area and cover with a gauze, twice a day. Strictly follow the instructions.
- ·Pay attention so that this ointment does not get in your eyes. If it gets in your eyes, wash it out immediately and consult with your doctor or pharmacist.
- ·If you miss a dose, apply the missed dose to the affected area when you remember. You should never 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

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include pain at the applied site, irritating sensation, bleeding and contact dermatitis. 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.
- •Discard the remainder. Do not store them. Consult with your pharmacy or medical institution about how to discard

## For healthcare professional use only

For further information, talk to your doctor or pharmacist.