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

External Revised: 03/2022

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:Borraza-G Ointment

Active ingredient: Tribenoside
Lidocaine

Dosage form: white to vellowish white ointment

Imprint or print on wrapping:ボラザ G 軟膏 (on a container and front of a sheet)



Effects of this medicine

This medicine improves the swelling and blood circulation disorder in the rectum/anus, and promotes the repair of the wound. It also resolves and relieves pain of the rectum/anus by surface anesthetic effect.

It is usually used to relieve the symptoms such as bleeding, pain, swelling associated with hemorrhoids (blind piles) and to relieve the symptoms such as bleeding, pain associated with anal fissure.

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 a history of allergic symptoms such as itch, rash due to foods, etc., allergic diseases such as bronchial asthma and allergic rhinitis, rheumatoid arthritis.
- · 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))
- For internal hemorrhoids (blind piles): In general, insert only the nozzle part and put the whole amount at one time in the anus in the morning and evening, twice a day. The frequency of doses may be adjusted according to the symptoms. Strictly follow the instructions.
- <u>For anal fissure and external hemorrhoids (blind piles)</u>: In general, apply or put an appropriate amount of the medicine to/into the affected area in the morning and evening, twice a day. The frequency of doses may be adjusted according to the symptoms. Strictly follow the instructions.
- •If you miss a dose, skip the missed dose and follow your regular dosing schedule. You should not use 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

• After using this medicine, white substances and oils may be mixed in the stool. It does not matter because that is melted oily or fatty base of this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, itch, irritation in the anus, diarrhea and dermatitis contact. If any of these symptoms occurs, 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.

•facial edema, breathing difficulty, hives [anaphylaxis]

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.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.