

## Disclaimer on Multilingual OTC Product Information

- This product is a pharmaceutical product approved under a Japanese law, the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices, with a view to its sale and use in Japan.
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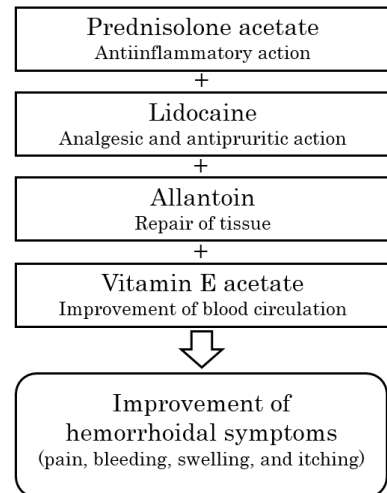
For relief of pain, bleeding, swelling, and itching due to hemorrhoids

# BORRAGINOL<sup>®</sup> A OINTMENT in Prefilled Disposable Applicators

[Category **2** OTC medicines]  
(External medicine for hemorrhoids)

## CHARACTERISTICS

- Four ingredients effectively act to relieve pain, bleeding, swelling, and itching due to hemorrhoids.**
  - Prednisolone acetate suppresses bleeding, swelling, and itching while lidocaine relieves pain and itching.
  - Allantoin accelerates wound healing and repairs damaged tissues while Vitamin E acetate helps to relieve the hemorrhoidal symptoms by improving blood circulation.
- This is a portable hemorrhoidal medicine convenient to use in the treatment of internal and external hemorrhoids.**
  - The product can be infused hygienically without touching the affected areas or the medicine with the hand directly.
- A smooth, little irritant, slippery oily base protects damaged lesion.**
  - The tip (nozzle) of the applicator is round shape to avoid damage on the affected areas.
  - This is a white to slightly yellowish white ointment.



## ⚠️ PRECAUTIONS

### ⊗ When not to use the product

(If you do not follow these instructions, the current symptoms may worsen or adverse reactions are more likely to occur.)

- This product should not be used in the following persons.**
  - Persons who have had an allergic symptom to this product or its ingredients.
  - Persons with purulent hemorrhoidal lesions.
- Do not use this product regularly for long periods.**

### 👤 Consultation

- The following persons should contact a physician, pharmacist, or registered salesperson for a consultation before use.**
  - Persons undergoing medical treatment from a physician.
  - Pregnant women or women suspected of being pregnant.
  - Persons who have experienced allergic symptoms associated with drugs, etc.
- If the following symptoms are observed after using this product, these may be adverse reactions, so immediately discontinue the use, and show this leaflet to your physician, pharmacist, or registered salesperson for a consultation.**

Affected parts	Symptoms
Skin	Rash/redness, itching, swelling
Others	Irritation, purulence

The following serious symptoms may occur in rare cases. In such cases, immediately seek medical aid.

Name of symptoms	Symptoms
Shock (Anaphylaxis)	Symptoms, such as itching of skin, urticaria, hoarseness, sneezing, itchy throat, breathing difficulties, palpitations, and clouding of consciousness may occur immediately after use.

3. When symptoms do not improve even after using this product for about 10 days, stop using this product and consult a physician, pharmacist or registered salesperson, being sure to take this leaflet with you.

## USES

Relief of pain, bleeding, swelling, and itching due to hemorrhoids (piles) and anal fissure

## DOSAGE AND DIRECTIONS

- Insert the nozzle part into the anus, and infuse the entire ointment slowly. (When infusing into the anus)

Age	Dose	Time of medication per day
Adults(15 years old and over)	1 applicator	1 to 2 times
Under 15 years old	This product should not be used.	

or

- Apply the following dose to the affected areas. Do not use the one used for topical application as an infusion. (When applying to the affected areas)

Age	Dose	Time of medication per day
Adults(15 years old and over)	Appropriate amount	1 to 3 times
Under 15 years old	This product should not be used.	

### <Precautions of dosage and directions>

- This product must be used only for the anal area.
- When infusing into the anus, insert the nozzle part only.
- Use this product strictly as directed under DOSAGE AND DIRECTIONS in this leaflet.

#### How to use the prefilled disposable applicator

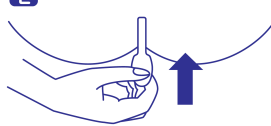
- This product is particularly effective if used after bowel movement or bathing, or at bedtime. -
- 【When infusing into the anus】

1



Remove the cap and squeeze out a small amount of the ointment on the tip of the nozzle.

2



Insert the nozzle part into the anus.

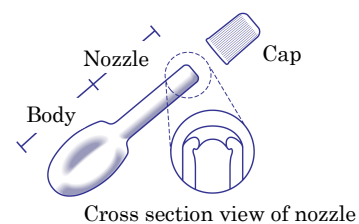
3



Squeeze the body to infuse the ointment slowly, and then pull the body out of the anus while squeezing it.

#### 【When applying to the affected areas】

Remove the cap, take an amount of ointment enough to cover the affected areas using a clean finger, and apply to the affected areas directly or by spreading on gauze, etc.



#### If the ointment becomes hard to squeeze out

The ointment may become too hard to squeeze out of the applicator during the cold season or when stored at low temperature. Warm it by holding with the hand until it becomes soft.

## INGREDIENTS per one applicator (2 g)

Actions	Ingredients	Contents (in 2 g)
Relief of bleeding, swelling, and itching by suppressing inflammation	Prednisolone acetate	1mg
Relief of local pain and itching	Lidocaine	60 mg
Acceleration of wound healing and repair of tissue	Allantoin	20 mg
Improvement of congestion by promoting peripheral blood circulation	Vitamin E acetate (Tocopherol acetate)	50 mg

Additives: White petrolatum, medium chain fatty acid triglyceride, glyceryl monostearate

- Because this product is applied by infusion, a small amount of the ointment will left in the applicator after infusion. Therefore, each applicator contains an extra amount estimated to remain in the applicator after the infusion.

## PRECAUTIONS FOR STORAGE AND HANDLING

- (1) Keep the cap tightly closed, and store in a cool place away from direct sunlight.
- (2) Keep out of reach of children.
- (3) Do not transfer the product to a different container. (It may lead to misuse or alter the quality of the product.)
- (4) Do not use this product after the expiration date.
- (5) Do not flush the used applicator and bag into a toilet.
- (6) This ointment is oil-based. If it is attached to clothes, it may become hard to remove.

## HOW SUPPLIED 10 and 30 applicators

### How to prevent hemorrhoids

- Prevent hemorrhoids by maintaining a healthy life style. -

- (1) To keep regular bowel movement, eat balanced meals three times a day.



- (2) Keep the anal area clean. Bathing is particularly effective in promoting blood circulation in the anus.



- (3) Avoid excessive strain during bowel movement.



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