

## **HEMORRHOIDAL-OINTMENT- lidocaine 4.00, phenylephrine hydrochloride**

### **0.25 ointment**

#### **Rrhoid Rage**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----

#### **Rrhoid Rage hemorrhoidal Ointment**

Lidocaine 4%.....Local Anesthetic

Phenylephrine Hydrochloride 0.25%.....Vasoconstrictor

Local anesthetic, Vasoconstrictor

- Helps relieve the pain, itching, and burning associated with hemorrhoids.
- Temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders.
- Temporarily provides a coating for relief of anorectal discomforts.
- Temporarily protects irritated areas and inflamed perianal skin.

#### **For external and/or intrarectal use only.**

#### **Ask a doctor before use if you have:**

- Heart disease; high blood pressure; thyroid disease; diabetes.
- Difficulty in urination due to enlargement of the prostate gland.

**Ask a doctor or pharmacist** before use if you are presently taking a prescription drug for high blood pressure or depression.

#### **When using this product**

- Avoid contact with eyes.
- Do not exceed recommended daily dosage unless directed by a doctor.
- Do not put this product into the rectum by using fingers or any mechanical device or applicator.

#### **Stop use and ask a doctor if**

- Bleeding occurs.
- Condition worsens or does not improve within 7 days.
- Allergic reaction occurs to ingredients in this product.
- Symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.

**If pregnant or breastfeeding**, ask a doctor before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

-When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly.

Gently dry by patting or blotting with toilet tissue or soft cloth before applying.

-Adults and children 12 years and older: apply externally to the affected area up to 4

times daily.

-Children under 12 years of age: consult a doctor.

### Other information

-Store at 20-25°C (68-77°F). Excursions permitted to 15-30°C (59-86°F).

aloe extract AQ, balsam fir, butylated hydroxyanisol, glycerin, lanolin alcohols, lanolin USP, magnesium sulfate, methyl paraben, mineral oil, petrolatum, propylparaben, witch hazel, white bees wax.



## HEMORRHOIDAL-OINTMENT

lidocaine 4.00, phenylephrine hydrochloride 0.25 ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82433-101
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	0.25 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>BALSAM FIR LEAFY TWIG</b> (UNII: H1TFV1454Z)	
<b>MAGNESIUM SULFATE, UNSPECIFIED</b> (UNII: DE08037SAB)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>LANOLIN ALCOHOLS</b> (UNII: 884C3FA9HE)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>ALOE</b> (UNII: V5VD430YW9)	
<b>SYNTHETIC BEESWAX</b> (UNII: 08MNR5YE2R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WITCH HAZEL</b> (UNII: 101I4J0U34)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82433-101-01	1 in 1 CARTON	06/06/2022	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/06/2022	

**Labeler** - Rrhoid Rage (035330878)

**Registrant** - Rrhoid Rage (035330878)

Revised: 6/2022

Rrhoid Rage