

**DERMFREE HEMORRHOID- lidocaine 4%, phenylephrine hcl 0.25%,
hemorrhoid ointment
Jiangxi Hemei Pharmaceutical Co., Ltd**

84010-022

Active Ingredient

Lidocaine 4%

Phenylephrine HCl 0.25%

Purpose

Analgesic (pain relief) Vasoconstrictor

Use

For external use only including the skin of the anal canal

Warnings

When using this product do not exceed recommended daily dosage unless directed by a doctor, when using finger cots or an applicator, apply externally or the skin of the anal canal only. Do not put this product into the rectum.

Do not use

Children under 12 years of age consult your pediatrician.

When Using

When using this product do not exceed recommended daily dosage unless directed by a doctor, when using finger cots or an applicator, apply externally or the skin of the anal canal only. Do not put this product into the rectum.

Stop Use

Ask a doctor before use if you have allergies to any of the components of this product, difficulty in urination due to enlargement of the prostate gland, diabetes, heart disease, high blood pressure, thyroid disease, or presently taking a prescription for high blood pressure or depression.

Ask Doctor

Stop use and ask a doctor if condition worsens or does not improve within seven days,

bleeding occurs, an allergic reaction develops, the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.

Keep Out Of Reach Of Children

If swallowed, seek medical help or contact a Poison Control Center right away.

Directions

Adults: apply to affected area up to 3 times daily. Clean affected area with mild soap and warm water, rinse thoroughly, and then gently dry (patting or blotting) with tissue or soft cloth before use.

To use dispensing cap, attach it to tube, lubricate well then gently insert part way into anus and squeeze tube to deliver medication. Thoroughly cleanse dispensing cap after use with mild soap and warm water and rinse thoroughly.

Other information

If pregnant or breast-feeding, ask a health care professional before use.

Inactive ingredients

Borneol, Carbomer Homopolymer, Chlorhexidine Acetate Glycerin, Thymol, Aloe

PRINCIPAL DISPLAY PANEL

DERMFREE™

HEMORRHOID OINTMENT
instructions

Drug Facts

-ACTIVE INGREDIENT
Lidocaine 4%.....**-PURPOSE**
Analgesic (pain relief)

Phenylephrine HCl 0.25%.....Vasoconstrictor

-INDICATIONS & USAGE
Temporarily shrinks hemorrhoidal tissue, for the temporary relief of pain, soreness, or burning, and helps relieve the local itching and discomfort associated with hemorrhoids.

-WARNINGS
For external use only including the skin of the anal canal. When using this product do not exceed recommended daily dosage unless directed by a doctor, when using finger coats or an applicator, apply externally or the skin of the anal canal only. Do not put this product into the rectum. Ask a doctor before use if you have allergies to any of the components of this product, difficulty in urination due to enlargement of the prostate gland, diabetes, heart disease, high blood pressure, thyroid disease, or presently taking a prescription for high blood pressure or depression. Stop use and ask a doctor if condition worsens or does not improve within seven days, bleeding occurs, an allergic reaction develops, the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.

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-PREGNANCY OR BREAST FEEDING
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DERMFREE™

HEMORRHOID OINTMENT
Medicine Contains Lidocaine and Phenylephrine HCl

- Soothing Pain Relief from Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves External Discomfort

NET: 1.5oz 42.5g

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DERMFREE™

Instantly Relieves Swelling, Pain, Itching & Burning

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84010-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
BORNEOL (UNII: M89NIB437X)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
THYMOL (UNII: 3J50XA376E)	
CHLORHEXIDINE ACETATE (UNII: 5908Z UF22Y)	
ALOE (UNII: V5VD430YW9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84010-022-01	42.5 g in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	08/15/2024	

Labeler - Jiangxi Hemei Pharmaceutical Co., Ltd (724892056)

Establishment

Name	Address	ID/FEI	Business Operations
Jiangxi Hemei Pharmaceutical Co., Ltd		724892056	manufacture(84010-022)

Revised: 8/2024

Jiangxi Hemei Pharmaceutical Co., Ltd