

**HEMORRHOIDAL PAIN RELIEF- hemorrhoidal pain relief cream cream
Neilmed Pharmaceuticals Inc.**

Hemorrhoidal Pain Relief Cream

Drug Facts:

Active Ingredients

Glycerin 14.4%

Phenylephrine HCl 0.25%

Pramoxine HCl 1%

Petrolatum 15%

Drug Facts:

Purpose

Protectant

Vasoconstrictor

Local Anesthetic

Protectant

Uses

- For temporary relief from pain and burning
- Helps relieve local itching and discomfort associated with hemorrhoids
- Temporarily shrinks hemorrhoidal tissue
- Temporarily provides a coating for relief of anorectal discomforts
- Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warnings:

For external 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 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:

- Do not exceed the recommended daily dosage unless directed by a doctor.
- Do not put in the rectum by using fingers or any mechanical device or applicator.

Stop use and ask doctor if:

- Bleeding occurs
- Condition worsens or does not improve within 7 days
- An allergic reaction occurs
- The symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase

If pregnant or breast-feeding,

Ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions:

- Adults: When practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe.
- Gently dry by patting or blotting with a tissue or a soft cloth before applying cream.
- When first opening the tube, puncture foil seal with top end of cap.
- Apply externally or in the lower portion of the anal canal only.
- Apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement.
- For application in the lower anal canal: Remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well using cream from the tube, then gently insert dispensing cap partway into anus. Thoroughly cleanse dispensing cap after each use and replace cover.
- Children under 12 years of age: ask a doctor.

Other information:

storage temperature: not to exceed 30°C (86°F). Protect from freezing.

Inactive ingredients:

Aloe vera leaf, butylated hydroxytoluene, cetostearyl alcohol, cetyl esters, cetyl

palmitate, glyceryl monostearate, isopropyl myristate, lanolin, methylparaben, mineral oil, polysorbate 60, propylene glycol, propylparaben, purified water, sodium citrate, stearic acid, tocopherol acetate

Questions or comments?

1 (877) 477-8633

TAMPER EVIDENT: DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING

Important:

Please do not discard this printed box and any enclosed printed material. The inside final product may not have all the details you require for the ongoing use of the product.



Active Ingredients: Glycerin 14.4%, Phenylephrine Hydrochloride 0.25%, Pramoxine Hydrochloride 1%, Petrolatum 15%.
Purpose: Protectant, Vasoconstrictor, Local Anesthetic, Protectant.
Uses: For temporary relief from pain and burning. Helps relieve local itching and discomfort associated with hemorrhoids. Temporarily shrinks hemorrhoidal tissue. Temporarily provides a coating for relief of anorectal discomforts. Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful.
Warnings: For external 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 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: Do not exceed the recommended daily dosage unless directed by a doctor. Do not put in the rectum by using fingers or any mechanical device or applicator.
Stop use and ask doctor if: Bleeding occurs, Condition worsens or does not improve within 7 days, An allergic reaction occurs, The symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).
Directions: Adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or a soft cloth before

applying cream. When first opening the tube, puncture foil seal with top end of cap. Apply externally or in the lower portion of the anal canal only. Apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement. For application in the lower anal canal: Remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing well, then gently insert dispensing cap partway into the anus. Thoroughly cleanse dispensing cap after each use and replace cover. Children under 12 years of age: ask a doctor.
Other information: storage temperature: not to exceed 30°C (86°F). Protect from freezing.
Inactive ingredients: aloe vera leaf, butylated hydroxytoluene, cetostearyl alcohol, cetyl esters, cetyl palmitate, glyceryl monostearate, isopropyl myristate, lanolin, methylparaben, mineral oil, polysorbate 60, propylene glycol, propylparaben, purified water, sodium citrate, stearic acid, tocopherol acetate.
Questions? 1 (877) 477-8633
TAMPER EVIDENT - DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING
Important: Please do not discard this printed box and any enclosed printed material. The inside final product may not have all the details you require for the ongoing use of the product.
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PK-TU078-Rev2 • NDC 13709-335-01
 LOT
 PLASTIC TUBE
 how2recycle.info

HEMORRHOIDAL PAIN RELIEF			
hemorrhoidal pain relief cream cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-335

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
GLYCERIN (UNII: PDC6A3C00X) (GLYCERIN - UNII:PDC6A3C00X)	GLYCERIN	144 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CETYL ESTERS (UNII: D072FFP9GU)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LANOLIN (UNII: 7EV65EAW6H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-335-01	1 in 1 CARTON	06/11/2025	
1		51 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 Drug	M015	06/11/2025	

Labeler - Neilmed Pharmaceuticals Inc. (799295915)

Establishment

Name	Address	ID/FEI	Business Operations
Neilmed Pharmaceuticals Inc.		799295915	manufacture(13709-335)

Revised: 9/2025

Neilmed Pharmaceuticals Inc.