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:

Store at 15°C – 30°C (59°F – 86°F)

Inactive ingredients:

Aloe vera leaf extract, 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

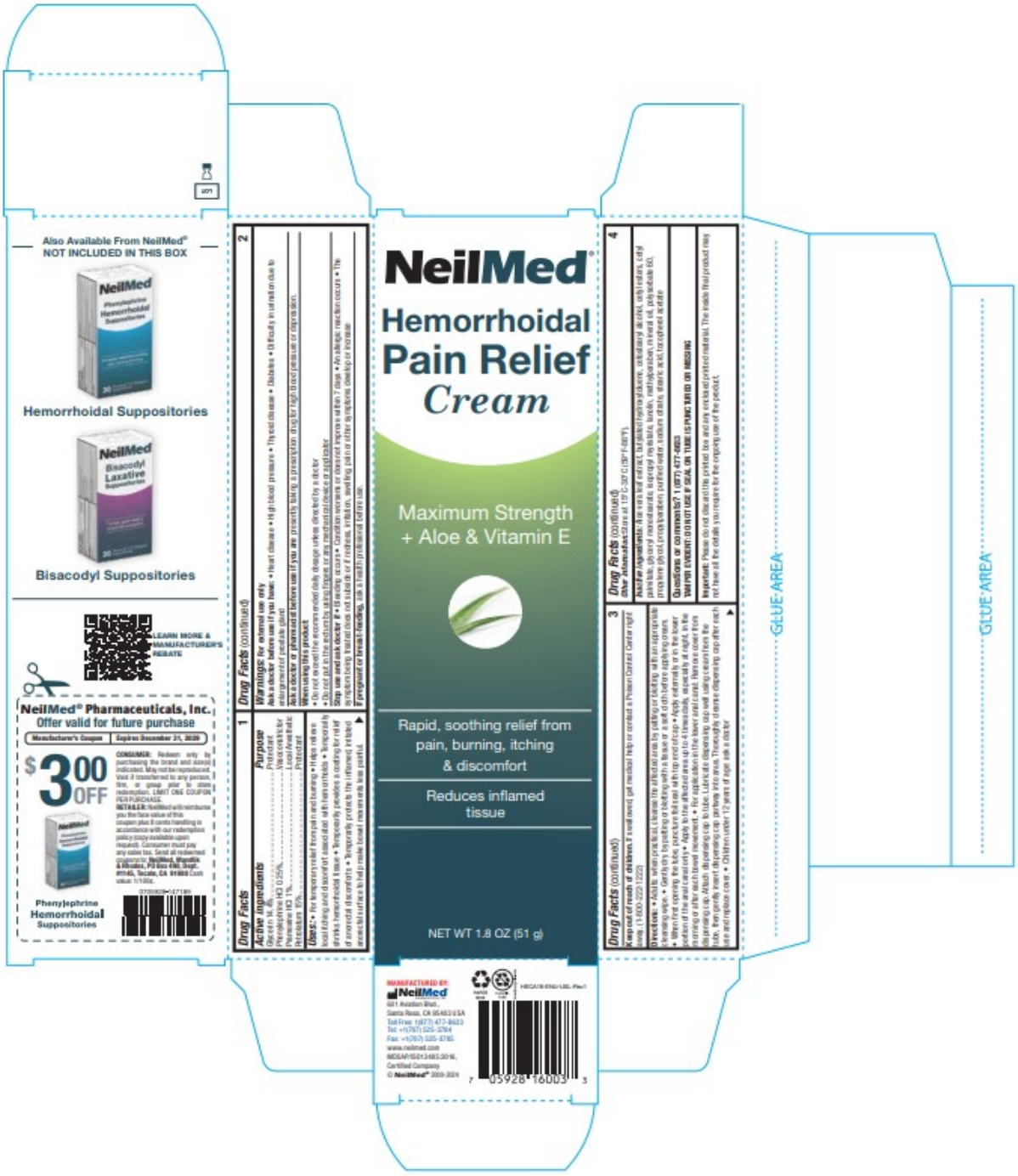
Questions or comments?

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.



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 -	PRAMOXINE	10 mg

UNII:068X84E056)	HYDROCHLORIDE	in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	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)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CETYL ESTERS (UNII: D072FFP9GU)	
WATER (UNII: 059QF0KO0R)	
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)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LANOLIN (UNII: 7EV65EAW6H)	

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)