HEMORRHOIDAL- pain relief ointment
NeilMed Pharmaceuticals Inc.

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.

Drug Facts

Active Ingredients

Mineral oil 14%

Petrolatum 74.9%
Phenylephrine Hydrochloride 0.25%

Active Ingredients Purpose
Mineral oil 14% ..... Protectant
Petrolatum 74.9%..... Protectant
Phenylephrine Hydrochloride 0.25% .....Vasoconstrictor

Uses

□□Helps relieve the local itching and discomfort associated with hemorrhoids.

□□Temporarily shrinks hemorrhoidal tissue and relieves burning.

□□Temporarily provides a coating for relief of anorectal discomforts.

□□Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful.

Warnings:

Warnings: For external and/or intrarectal use only

Ask a doctor before use if you have:

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

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.

Stop use and ask doctor if:

Stop use and ask doctor if: □□Bleeding occurs □□Condition worsens or does not improve within 7 days
□□Introduction of applicator into the rectum causes additional pain.

If pregnant or breast-feeding,

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

Keep out of reach of children

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 ointment.

□□When first opening the tube, puncture foil seal with top end of cap apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement.

□□Intrarectal use: remove cover from applicator, attach applicator to tube, lubricate applicator well and gently insert applicator into the rectum; thoroughly cleanse applicator after each use and replace cover.

□□Also apply ointment to external area.

□□Regular use provides continual therapy for relief of symptoms.

□□Children under 12 years of age: ask a doctor.

Other information:

Store at 15°C - 30°C (59°F - 86°F).

Inactive ingredients:

Benzoic acid, butylated hydroxytoluene, corn oil, glycerin, lanolin, lanolin alcohol, methylparaben, propylparaben, paraffin wax, purified water, thymus vulgaris oil, tocopherol acetate, white wax

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

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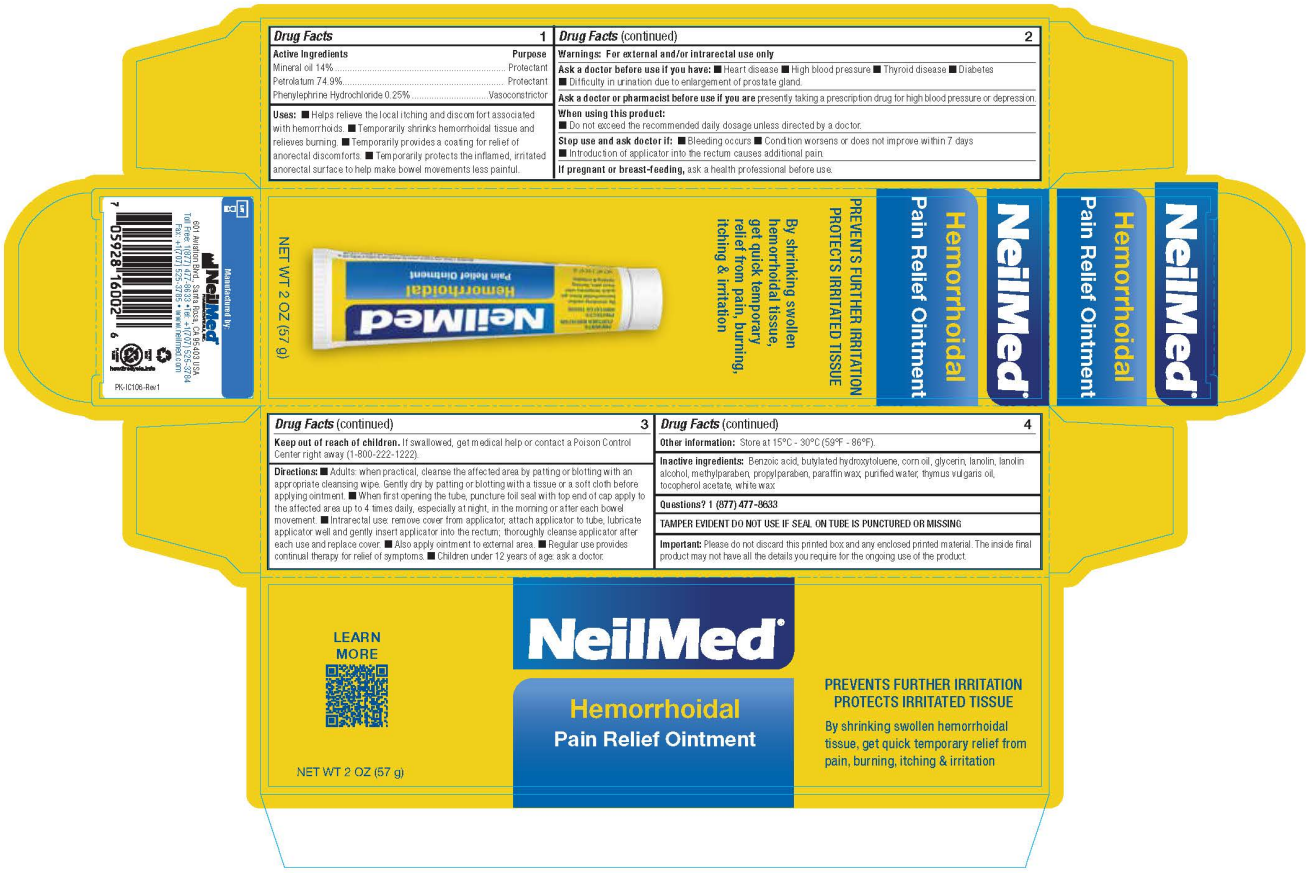
Important: Please do not discard this printed box and any enclosed printed material. The inside final
product may not have all the details you require for the ongoing use of the product.



HEMORRHOIDAL

pain relief ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13709-319
Route of Administration	RECTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	749 mg in 1 g
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PARAFFIN (UNII: I9O0E3H2ZE)	
LANOLIN (UNII: 7EV65EAW6H)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
CORN OIL (UNII: 8470G57WFM)	
WHITE WAX (UNII: 7G1J5DA97F)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
THYME (UNII: CW657OBU4N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-319-01	1 in 1 CARTON	08/22/2023	
1		57 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	M015	08/22/2023	

Labeler - NeilMed Pharmaceuticals Inc. (799295915)

Establishment

Name	Address	ID/FEI	Business Operations
NeilMed Pharmaceuticals Inc.		799295915	manufacture(13709-319)

Revised: 8/2023 NeilMed Pharmaceuticals Inc.