

COOLING GEL- pain relief cooling gel gel
Neilmed Pharmaceuticals Inc.

Cooling Gel

Drug Facts: Active Ingredients

Phenylephrine HCl 0.25%

Witch Hazel 50.5%

Purpose

Vasoconstrictor

Astringent

Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- provides temporary relief from irritation and burning
- temporarily provides a cooling coating for relief of anorectal discomforts

Warnings

For External Use Only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- diabetes
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland unless directed by a doctor

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
- in case of bleeding, consult a doctor promptly

Stop use and ask a doctor if

condition worsens or does not improve within 7 days

If pregnant or breastfeeding,

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 soft cloth before applying gel
- When first opening the tube, puncture foil seal with the top end of the cap
- Apply externally to the affected area up to 4 times daily
- **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 barbadensis leaf extract, edetate disodium, hydroxyethyl cellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben, purified water, sodium citrate, sulisobenzene, tocopheryl acetate (vitamin E).

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

COOLING GEL

pain relief cooling gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-346
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 101I4J0U34) (WTCH HAZEL - UNII:101I4J0U34)	WTCH HAZEL	505 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE BARBADENSIS LEAF (UNII: ZY81Z83H0X)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SULISOBENZONE (UNII: 1W6L629B4K)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-346-01	1 in 1 CARTON	11/13/2025	
1		25.5 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	11/13/2025	

Labeler - Neilmed Pharmaceuticals Inc. (799295915)

Establishment

Name	Address	ID/FEI	Business Operations
Neilmed Pharmaceuticals Inc.		799295915	manufacture(13709-346)

Revised: 11/2025

Neilmed Pharmaceuticals Inc.