

HEMORRHOIDAL PAIN RELIEF WITH ALOE AND VITAMINE- hemorrhoidal pain relief with aloe and vitamine cream

NeilMed pharmaceuticals Inc.

Hemorrhoidal Pain Relief Cream with Aloe and Vitamin E

Drug Facts - Active Ingredients

Glycerin 14.4%
Phenylephrine Hydrochloride 0.25%
Pramoxine Hydrochloride 1%
White petrolatum 15%

Purpose

Glycerin 14.4% Protectant
Phenylephrine Hydrochloride 0.25%Vasoconstrictor
Pramoxine Hydrochloride 1% Local Anesthetic
White petrolatum 15% Protectant

Uses:

For temporary relief of pain, soreness and burning. Helps relieve the 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

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.

Inactive ingredients:

aloe barbadensis 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?

Questions? 1 (877) 477-8633

TAMPER EVIDENT:

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

Important

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.

Use

swollen hemorrhoidal tissue, to get quick temporary relief from pain, burning, itching& irritation

Package label _Outer carton

HEMORRHOIDAL PAIN RELIEF WITH ALOE AND VITAMINE

hemorrhoidal pain relief with aloe and vitamine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-324
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	25 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	144 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE (UNII: V5VD430YW9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-324-01	1 in 1 CARTON	10/11/2023	
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	10/11/2023	

Labeler - NeilMed pharmaceuticals Inc. (799295915)**Establishment**

Name	Address	ID/FEI	Business Operations
NeilMed Pharmaceuticals Inc.		799295915	manufacture(13709-324)

Revised: 10/2023

NeilMed pharmaceuticals Inc.