

HEMOTREAT- white petrolatum, lanolin, hard fat, camphor cream

Global Treat srl

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.

HemoTreat (69758-322)

Drug Facts

Active Ingredients

White Petrolatum 21.3% wt/wt

Lanolin 21.25% wtwt

Hard Fat 42.6% wt/wt

Camphor 2.5% wt/wt

Purposes

Protectant

Protectant

Protectant

Analgesic

Uses

- helps relieve itching and discomfort associated with hemorrhoids and anorectal disorders
- temporarily relieves pain associated with anorectal inflammation and inflamed hemorrhoidal tissues
- may provide cooling sensation

Warnings

For rectal use only

- **Do not use** for more than 30 days
- **When using this product** do not exceed the recommended daily dosage, unless directed by a doctor

Stop use and ask a doctor if:

- bleeding occurs
- condition worsens or does not improve within seven days
- signs of a local infection appear
- Certain person can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside of if redness, irritation, swelling, pain, and or other symptoms develop or increase, **discontinue use and consult a doctor.**

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

Keep out of the 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 with mild soap and warm water
- gently dry by patting or blotting with toilet tissue or a soft cloth before application of ointment
- with the help of the index finger, apply a thin layer of ointment
- apply 2 times a day, morning and evening, for 5-7 days. Spread on to the affected area, generally on the exterior of the anus and in the vicinity of the anal orifice

Children under 12 years

- consult a doctor

Other Information

- store at 15-25°C (59-77°F)
- protect from excessive moisture
- keep away from direct sunlight

Inactive Ingredients

butylated hydroxyl anisole, calcium carbonate, ethanol, ethylparaben, eucalyptus oil, methylparaben, phenoxyethanol

Manufactured by SC Global Treat SRL

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Principal Display Panel

NDC 69758-322-55

HemoTreat

Hemorrhoidal Ointment

H

50 ml



HEMOTREAT

white petrolatum, lanolin, hard fat, camphor cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69758-322
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	0.213 g in 1 g
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	0.212 g in 1 g

FAT, HARD (UNII: 8334LX7S21) (FAT, HARD - UNII:8334LX7S21)	FAT, HARD	0.420 g in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.025 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
ALCOHOL (UNII: 3K9958V90M)	
ETHYLPARABEN (UNII: 14255EXE39)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69758-322-55	50 g in 1 JAR; Type 0: Not a Combination Product	05/15/2015	02/15/2018
2	NDC:69758-322-71	1 in 1 CARTON	06/01/2016	
2		28.3 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	05/15/2015	

Labeler - Global Treat srl (505948710)

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