HEMO FIN - petrolatum ointment PD MERC LLC

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.

Hemo-Fin Hemorrhoidal Ointment

Active ingredient

Petrolatum (93.3%)

Purpose

Hemorrhoidal ointment

Uses

- Provides temporary relief from skin irritations
- Temporarily forms a protective coating over inflamed tissues to help prevent drying of tissues
- Temporarily protects irritated areas
- Temporarily relieves burning
- Temporarily provides a coating for relief of anorectal discomforts
- Temporarily protects the inflamed, irritated, anorectal surface from irritation and abrasion during bowel movement
- Temporarily protects inflamed perianal skin
- Temporarily relieves symptoms of perianal skin irritation

Warnings

For external and/or intrarectal use only

If condition worsens or does not improve within 7 days, consult a physician

Do not exceed the recommended daily dosage unless directed by a doctor

In case of bleeding, consult a physican promptly

Do not use

this product with an applicator if the introduction of the applicator into the rectum causes additional pain. Consult a doctor promptly.

Keep Out Of Reach of Children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly or by patting or blotting with an appropriate cleansing wipe before applying ointment.
- Apply liberally to affected area as often as necessary.
- Intrarectal Use: attach applicator to tube, lubricate applicator well and gently insert applicator into

rectum. Thoroughly cleanse applicator after each use.

Inactive Ingredients

Aloe Vera, Iodine, Okra, Oleic Acid, Sage

For Questions or Comments:

PDmerc.com

Distributed by

P D Merc, LLC

1581 W 49th St #191

Hialeah, FL 33012

NDC 50211-001-01

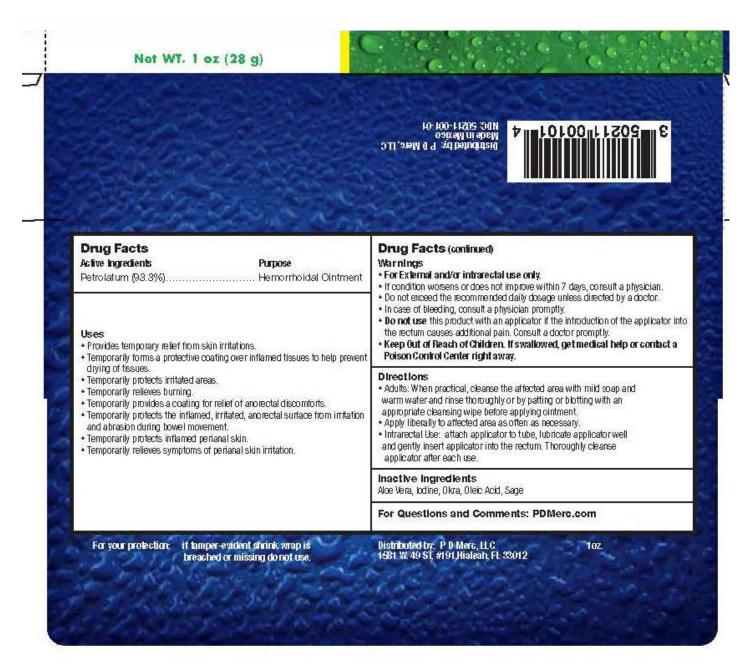
Hemo-Fin

Hemorrhoidal Oitment

Net Wt. 1 oz. (28 g)

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HEMO FIN

petrolatum ointment

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50211-001	
Route of Administration	RECTAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petro latum	93.3 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
Aloe Vera Leaf (UNII: ZY81Z83H0X)			
Iodine (UNII: 9679TC07X4)			
Okra (UNII: 51ME2L7STL)			
Oleic Acid (UNII: 2UMI9 U37CP)			
Sage (UNII: 065C5D077J)			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50211-001-01	28 g in 1 TUBE, WITH APPLICATOR		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part346	09/10/2012		

Labeler - PD MERC LLC (078424706)

Establishment				
Name	Address	ID/FEI	Business Operations	
Farmaco Drogueria Leque, S.A. de C.V.		8 148 6 1357	manufacture (50211-001)	

Revised: 9/2012 PD MERC LLC