

PREMIER VALUE HEMORRHOIDAL- mineral oil, petrolatum, and phenylephrine hydrochloride ointment

Chain Drug Consortium, 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.

Active ingredients	Purpose
Mineral Oil 14%.....	Protectant
Petrolatum 74.9%.....	Protectant
Phenylephrine HCl 0.25%.....	Vasconstrictor

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 surface to help make bowel movements less painful

Warnings

For external and/or intrarectal use only

Ask a doctor or pharmacist before use if you are now 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 a doctor if

- bleeding occurs
- condition gets worse or does not get better within 7 days
- introduction of the applicator into the rectum causes additional pain

If pregnant or breast-feeding, ask a physician before use

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- children under 12 years of age: ask a doctor
- 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
- when first opening tube, remove foil seal
- for intrarectal use: remove protective cover from applicator and attach to tube
- lubricate well, then gently insert applicator into the rectum
- thoroughly clean applicator and replace protective cover after each use
- apply externally to the affected area up to 4 times daily, especially at night, in the morning, or after each bowel movement
- also apply to external area

Other information

- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

glycerin, lanolin, methylparaben, propylparaben, stearyl alcohol, thyme oil, tocopherol acetate, water, white wax

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CHAIN DRUG CONSORTIUM

3301 NW BOCA RATON BLVD

SUITE 101

BOCA RATON, FL 33431

MADE IN KOREA

Drug Facts (continued)
get better within 7 days • introduction of the applicator into the rectum causes additional pain. If pregnant or breast-feeding, ask a physician before use. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

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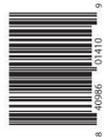
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Vasoconstrictor

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Drug Facts (continued)
Warnings For external and/or intrarectal use only
Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland
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Rev 09/12

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PREMIER VALUE HEMORRHOIDAL

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Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:680 16-840

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
THYME OIL (UNII: 2UK410MY6B)	
WATER (UNII: 059QF0K00R)	
WHITE WAX (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-840-57	1 in 1 CARTON		
1		57 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	02/11/2015	

Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 2/2015

Chain Drug Consortium, LLC