

QUALITY CHOICE HEMORRHOIDAL- mineral oil ointment
Chain Drug Marketing Association

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.

QC Hemorrhoidal Ointment 2oz (with applicator) NBE Preparation H 95128 ZDP

Active ingredients	Purpose
Mineral oil 14%.....	Protectant
Petrolatum 74.9%.....	Protectant
Phenylephrine HCl 0.25%.....	Vasoconstrictor

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 anorectal surface to help make bowel movements less painful

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

Ask a doctor or a pharmacist before use if you are now taking a prescription drug for high blood pressure or depression

When using this product do not use more than 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

- 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 ointment.
- when first opening the tube, peel back foil seal
- apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- intrarectal use:
- remove cover from applicator, attach applicator to tube, lubricate applicator well and gently insert applicator into the rectum

- thoroughly cleanse applicator after each use and replace cover
- also apply ointment to external area
- regular use provides continual therapy for relief of symptoms
- children under 12 years of age: ask a doctor

Other information store at 20° to 25°C (68° to 77°F)

Inactive ingredients .alpha.-tocopherol acetate, alcohol, glycerin, lanolin, methylparaben, polysorbate 80, propylparaben, alcohol, thyme oil, purified water, white wax

Distributed by:

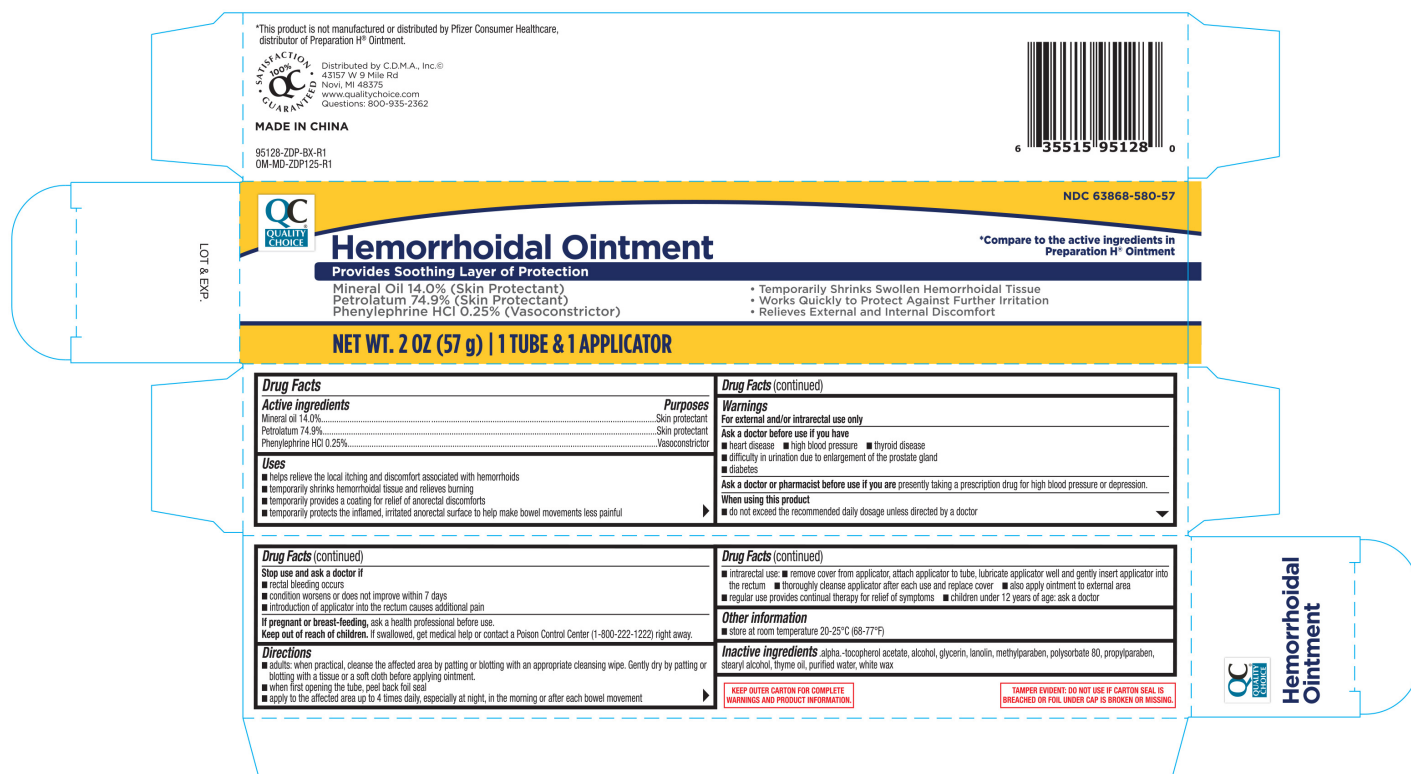
C.D.M.A., Inc.

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Made in China



QUALITY CHOICE HEMORRHOIDAL

mineral oil ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-580
Route of Administration	TOPICAL, RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
		14.0 mg

MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140 mg in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	749 mg in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7H9T)	
ALCOHOL (UNII: 3K9958V90M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
THYME OIL (UNII: 2UK410MY6B)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-580-57	1 in 1 CARTON	01/07/2020	
1		57 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 final	part346	06/30/2013	

Labeler - Chain Drug Marketing Association (011920774)

Revised: 2/2020

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