

QUALITY CHOICE HEMORRHOIDAL - mineral oil, petrolatum, phenylephrine hcl, shark liver oil ointment

CHAIN DRUG MARKETING ASSOCIATION INC

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.

Drug Facts

Active ingredients	Purpose
Mineral oil 14%	Protectant
Petrolatum 71.9%	Protectant
Phenylephrine HCL 0.25%	Vasoconstrictor
Shark liver oil 3.0%	Protectant

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 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

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 a soft cloth before applying
- when first opening tube, remove foil seal
- for intrarectal use: remove protective cover from applicator and attach to tube
- lubricate applicator 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 ointment to external area

Other information

Store at 20° to 25°C (68° to 77°F)

Inactive ingredients

benzoic acid, BHA, BHT, methylparaben, paraffin, propylparaben, thyme oil, glyceryl stearate, glycerin, absorb refined lanoline, purified water

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NOVI, MI 48376-0995

QC 95128

www.qualitychoice.com

Made in Korea

<p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have <input type="checkbox"/> heart disease <input type="checkbox"/> high blood pressure <input type="checkbox"/> thyroid disease <input type="checkbox"/> diabetes <input type="checkbox"/> trouble urinating due to an enlarged prostate gland</p> <p>Ask a doctor or pharmacist before use if you are now taking a prescription drug for high blood pressure or depression</p> <p>When using this product do not use more than the recommended daily dosage</p> <p>Stop use and ask a doctor if <input type="checkbox"/> bleeding occurs <input type="checkbox"/> condition gets worse or does not get better within 7 days <input type="checkbox"/> introduction of the applicator into the rectum causes additional pain</p> <p>If pregnant or breast-feeding, ask a physician before use. ▶</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions <input type="checkbox"/> children under 12 years of age: ask a doctor <input type="checkbox"/> adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe <input type="checkbox"/> gently dry by patting or blotting with a tissue or a soft cloth before applying <input type="checkbox"/> when first opening tube, remove foil seal <input type="checkbox"/> for intrarectal use: remove protective cover from applicator and attach to tube <input type="checkbox"/> lubricate applicator well, then gently insert applicator into the rectum <input type="checkbox"/> thoroughly clean applicator and replace protective cover after each use</p>	10-298C32QCCHT										
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 <p>HEMORRHOIDAL OINTMENT</p> <p>Helps Prevent Further Irritation</p> <ul style="list-style-type: none"> • For Prompt Temporary Relief • Reduces Swelling • Soothes itching, burning and discomfort associated with hemorrhoids <p>Net Wt 2 oz (56.8 g)</p> <p><small>*Compare to the Active Ingredients in Preparation H®</small></p>												
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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-951

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	719 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
SHARK LIVER OIL (UNII: 4B24275HEU) (SHARK LIVER OIL - UNII:4B24275HEU)	SHARK LIVER OIL	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
THYME OIL (UNII: 2UK410MY6B)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-951-57	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	03/01/2012	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Revised: 3/2012

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