

FAMILY CARE HEMORRHOIDAL - mineral oil, petrolatum, phenylephrine hcl, shark liver oil ointment

UNITED EXCHANGE CORP.

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)

Lot No. and Exp. Date: see box or see crimp of tube

Inactive ingredients

BHA, concentrated glycerin, glyceryl monosterate, methylparaben, propylparaben, purified lanoline, purified water, thyme oil red

Distributed By:

UNITED EXCHANGE CORP.

17211 Valley View Ave.

Cerritos, CA 90703 USA

Made in Korea



*Compare to the active ingredients of Preparation H® Ointment

Prevents Further Irritation

HEMORRHOIDAL

Ointment With Applicator

• Prompt Soothing Relief From Painful Burning, Itching And Discomfort

• Shrinks Swollen Hemorrhoidal Tissue

Prevents Further Irritation

HEMORRHOIDAL

Ointment With Applicator

HEMORRHOIDAL

Ointment With Applicator

• Shrinks Swollen Hemorrhoidal Tissue
• Prompt Soothing Relief From Painful Burning, Itching & Discomfort
• Relieves External Discomfort & Protects Irritated Tissue



NET WT 0.67 OZ (20g)

LOT & EXP.

*This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Preparation H® Ointment.

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<p>Drug Facts</p> <p>Active ingredients</p> <ul style="list-style-type: none"> Mineral oil 14% Proctant Vasconstant Proctant Shark liver oil 3.0% <p>Purpose</p> <p>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 relieves the inflamed, irritated anorectal surface to help make bowel movements less painful</p> <p>Warnings</p> <p>For external use only / or intrarectal use only</p> <p>Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ 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 unless directed by a doctor</p> <p>Stop use and ask a doctor if ■ bleeding occurs ■ condition gets worse or does not get better within 7 days</p> <p>If pregnant or breast-feeding, ask a physician before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <p>children under 12 years of age: ask a doctor</p> <p>adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe</p> <p>gently dry by patting or blotting with a tissue or a soft cloth before applying ointment</p> <p>when first opening tube, remove foil seal</p> <p>apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement</p> <p>for intrarectal use: remove protective cover from applicator and attach applicator to tube</p> <p>lubricate applicator well, then gently insert applicator into the rectum</p> <p>thoroughly clean applicator and replace protective cover after each use</p> <p>also apply ointment to external area</p> <p>regular use provides continual therapy for relief of symptoms</p> <p>Other information</p> <ul style="list-style-type: none"> store at 20°C-25°C (68°F-77°F) Lot No. & Exp. Date: see box or see crimp of tube <p>Inactive ingredients</p> <p>purified lanolin, purified water, thyme oil red, glycerin, butylated hydroxytoluene, concentrated glycerin, butylated hydroxytoluene, methylparaben, propylparaben.</p>
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FAMILY CARE HEMORRHOIDAL

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-009
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
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
LANOLIN (UNII: 7EV65EAW6H)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-009-20	1 in 1 CARTON		
1		20 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 - UNITED EXCHANGE CORP. (840130579)

Revised: 3/2012

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