

FAMILY CARE HEMORRHOIDAL- mineral 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.

Family Care Hemorrhoidal Ointment 0.67oz (with applicator) 515

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 relieve 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 use only / or intrarectal use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland
- diabetes

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

- rectal bleeding occurs
- condition gets worse or does not get better within 7 days
- introduction of 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 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° C to 25°C (68° to 77°F)

Inactive ingredients

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

Distributed by:

United Exchange Corp

Cypress, CA 90630 USA

Made in China

FAMILY CARE™

*Compare to the active ingredients of PREPARATION H® Ointment

HEMORRHOIDAL OINTMENT WITH APPLICATOR

- For Prompt Temporary Relief of:
- Hemorrhoidal Pain
 - Itching
 - Burning

- Mineral Oil 14.0% (Skin Protectant)
- Petrolatum 74.9% (Skin Protectant)
- Phenylephrine Hcl 0.25% (Vasoconstrictor)



For Prompt Temporary Relief of:

- Hemorrhoidal Pain
- Itching
- Burning

ORIGINAL

HEMORRHOIDAL OINTMENT WITH APPLICATOR

- Mineral Oil 14.0% (Skin protectant)
- Petrolatum 74.9% (Skin protectant)
- Phenylephrine HCl 0.25% (Vasoconstrictor)

1 TUBE - NET WT. 0.71 OZ (20 g)

FAMILY CARE™



Distributed By: UNITED EXCHANGE CORP. Cypress, CA 90630 USA
1-888-645-8204 | 515-ZDP-BX-R2 | OM-MD-ZDP125-R1
Made In China

*This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Preparation H® Ointment.

LOT & EXP.

Drug Facts (continued)

Purposes
Mineral oil 14.0%
Skin protectant
Petrolatum 74.9%
Phenylephrine HCl 0.25%
Vasoconstrictor

Active ingredients
Mineral oil 14.0%
Petrolatum 74.9%
Phenylephrine HCl 0.25%
Vasoconstrictor

Uses
relieve the local itching and discomfort associated with hemorrhoids
temporarily soothes 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 internal use only
Ask a doctor before use if you have
heart disease ■ high blood pressure ■ thyroid disease
■ difficulty in urination due to enlargement of the prostate gland
■ diabetes
Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.
Do not exceed the recommended daily dosage unless directed by a doctor.
Stop use and ask a doctor if
■ rectal bleeding occurs
■ condition worsens or does not improve within 7 days
■ pain

Directions
adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry the area.
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.
interrectal use: ■ remove applicator from applicator, attach applicator to tube, lubricate applicator well and gently insert applicator into the rectum
thoroughly cleanse applicator after each use and replace applicator
righter use provides optimal therapy for relief of symptoms
children under 12 years of age, ask a doctor

Other information
store at room temperature 20-25°C (68-77°F)

Inactive ingredients alpha-tocopherol acetate, alcohol, glycerin, lanolin, methylparaben, polyoxylated 80, propylparaben, stearyl alcohol, thymol, white wax

Questions or comments?
Call 1-888-645-8204

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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FAMILY CARE™

FAMILY CARE HEMORRHOIDAL

mineral oil ointment

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:65923-003

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 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: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
THYME OIL (UNII: 2UK410MY6B)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-003-20	1 in 1 CARTON	11/24/2014	
1		20 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	11/24/2014	

Labeler - United Exchange Corp (840130579)