

WINCO HEMORRHOIDAL- mineral oil, petrolatum, and phenylephrine hydrochloride cream
Winco Foods, 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.

Winco Hemorrhoidal Ointment 2 oz, ZDP

Active ingredients Purposes

Mineral oil 14.0%.....Skin protectant
Petrolatum 74.9%.....Skin 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
- 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.

When using this product

- 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
- introduction of applicator into the rectum causes additional pain

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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 ask a doctor

Other information:

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

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

DISTRIBUTED BY:

WINCO FOODS, LLC,

BOISE, ID 83704

MADE IN CHINA

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 *This product is not manufactured or distributed by PFIZER CONSUMER HEALTHCARE, distributor of PREPARATION H® Ointment.
 24195-ZDP-BX-R1
 0M-IMP-ZDP125-R1

The Supermarket Low Price Leader®
100% SATISFACTION GUARANTEE
 Comments & Questions?
 800-824-1706 • www.wincofoods.com

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
 TAMPER EVIDENT: DO NOT USE IF CARTON SEAL IS BREACHED OR FOIL UNDER CAP IS BROKEN OR MISSING.

EMPLOYEE-OWNED CERTIFIED
 PLEASE RECYCLE CARDBOARD CARTON

0 70552 24195 4

Lot & Exp.

WinCo FOODS
Hemorrhoidal Ointment
 MINERAL OIL & PETROLATUM/SKIN PROTECTANT • PHENYLEPHRINE HCl/VASOCONSTRICTOR
 NET WT 2 OZ (57 g)

*Compare to the active ingredients in PREPARATION H® Ointment
 Prompt Soothing Relief from Painful Burning, Itching, Discomfort and Irritated Tissue

 Applicator Included

<p>Drug Facts</p> <p>Active ingredients</p> <p>Mineral oil 14.0% Petrolatum 74.9% Phenylephrine HCl 0.25%</p> <p>Purposes</p> <p>Skin protectant Skin protectant Vasoconstrictor</p> <p>Uses</p> <ul style="list-style-type: none"> ■ 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 	<p>Drug Facts (continued)</p> <p>Warnings For external and/or intrarectal use only</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ heart disease ■ high blood pressure ■ thyroid disease ■ difficulty in urination due to enlargement of the prostate gland ■ diabetes <p>Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ do not exceed the recommended daily dosage unless directed by a doctor
<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ rectal bleeding occurs ■ condition worsens or does not improve within 7 days ■ introduction of applicator into the rectum causes additional pain <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ 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 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ 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 <p>Other information</p> <ul style="list-style-type: none"> ■ store at room temperature 20-25°C (68-77°F) <p>Inactive ingredients alpha.-tocopherol acetate, alcohol, glycerin, lanolin, methylparaben, polysorbate 80, propylparaben, stearyl alcohol, thyme oil, purified water, white wax</p> <p>Questions? Call 800-824-1706 Monday-Friday 9am - 4pm MST</p>

WinCo FOODS
Hemorrhoidal Ointment

WINCO HEMORRHOIDAL

mineral oil, petrolatum, and phenylephrine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-278
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	749 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
THYME OIL (UNII: 2UK410MY6B)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WHITE WAX (UNII: 7G1J5DA97F)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-278-57	1 in 1 CARTON	01/29/2015	
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	01/29/2015	

Labeler - Winco Foods, LLC (056098817)