

HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hcl ointment

Meijer Distribution 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.

Meijer Distribution, Inc. Hemorrhoidal Ointment Drug Facts

Active ingredients

Mineral oil 14%

Petrolatum 74.9%

Phenylephrine HCl 0.25%

Purposes

Protectant

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
- difficulty in urination due to enlargement of the prostate gland

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

- 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 right away. (1-800-222-1222)

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, puncture foil seal with top end of cap
- 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

Inactive ingredients

benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, thymus vulgaris (thyme) oil, tocopheryl acetate, white wax

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Preparation H[®] active ingredients

hemorrhoidal ointment

Mineral Oil | Petrolatum

Phenylephrine HCl

Prevents Further Irritation

PROTECTS IRRITATED TISSUE

Prompt, Soothing Relief from Painful Burning, Itching & Discomfort

Shrinks Swollen Hemorrhoidal Tissue

Relieves Internal & External Discomfort

NET WT 2 OZ (57 g)

meijer

NDC 41250-188-16
Compare to Preparation H® active ingredients*

hemorrhoidal ointment

Mineral Oil | Petrolatum
Phenylephrine HCl

Prevents Further Irritation

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Inactive ingredients benzoic acid, butylated hydroxyanisole, com oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, parafin, propylparaben, purified water, thymus vulgaris (thyme) oil, tocopheryl acetate, white wax

Questions or comments? 1-800-719-9260

*This product is not manufactured or distributed by Wyeth LLC, owner of the registered trademark Preparation H®.

Store at 20-25°C (68-77°F)

DO NOT USE IF TUBE SEAL IS BROKEN OR MISSING

NDC 41250-188-16
Compare to Preparation H® active ingredients*

hemorrhoidal ointment

Mineral Oil | Petrolatum | Phenylephrine HCl

Relieves Internal & External Discomfort | Prevents Further Irritation

PROTECTS IRRITATED TISSUE

NET WT 2 OZ (57 g)

meijer

DIST. BY MEIJER DISTRIBUTION, INC.
GRAND RAPIDS, MI 49544
www.meijer.com



PID 346805



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HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hcl ointment

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41250-188 |
| Route of Administration | RECTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|-----------------|
| MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP) | MINERAL OIL | 14 g in 100 g |
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 74.9 g in 100 g |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | .25 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U) | |
| CORN OIL (UNII: 8470G57WFM) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| LANOLIN (UNII: 7EV65EAW6H) | |
| LANOLIN ALCOHOLS (UNII: 884C3FA9HE) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PARAFFIN (UNII: I9O0E3H2ZE) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |
| THYME OIL (UNII: 2UK410MY6B) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| WHITE WAX (UNII: 7G1J5DA97F) | |

Product Characteristics

| | | | |
|-----------------|----------------|---------------------|--|
| Color | YELLOW (light) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|---|------------------|---|------------|--|
| 1 | NDC:41250-188-16 | 1 in 1 CARTON | 03/05/2014 | |
| 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 | 03/05/2014 | |

Labeler - Meijer Distribution Inc (006959555)

Revised: 3/2019

Meijer Distribution Inc