

**WESTERN FAMILY HEMORRHOIDAL - mineral oil, petrolatum, phenylephrine hcl ointment
WESTERN FAMILY FOOD, 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 |

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 form 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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| WESTERN FAMILY HEMORRHOIDAL | | | |
|---|-------------------|--------------------|---------------|
| mineral oil, petrolatum, phenylephrine hcl ointment | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55312-034 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| MINERAL OIL (UNII: T51 8T28 ECD) (MINERAL OIL - UNII: T51 8T28 ECD) | MINERAL OIL | 140 mg | |

| | | |
|--|--------------------------------|------------------|
| MINERAL OIL (UNII: 15L6128FGF) (MINERAL OIL - UNII:15L6128FGF) | MINERAL OIL | 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 |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:55312-034-02 | 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 | 07/31/2012 | |

Labeler - WESTERN FAMILY FOOD, INC. (192166072)

Revised: 7/2012

WESTERN FAMILY FOOD, INC.