WALGREENS MAXIMUM STRENGTH HEMORRHOIDAL- glycerin, phenylephrine hcl, pramoxine hcl, and white petrolatum cream Walgreen Company

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.

Walgreens Hemorrhoidal Cream 0.9OZ (with applicator) 902035 (2018)

| Active ingredients | Purpose |
|-------------------------|-------------------|
| Glycerin 14.4% | Protectant |
| Phenylephrine HCL 0.25% | Vasoconstrictor |
| Pramoxine HCL 1% | Local anaesthetic |
| White petrolatum 15% | Protectant |

Uses

- for temporary relief of pain, soreness and burning
- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- 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

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficult 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
- do not put into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- bleeding occurs
- condition worsens or does not improve within 7 days
- an allergic reaction develops
- the symptoms being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase

If pregnant or breask-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

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 cream
- when first opening the tube, puncture foil seal with top end of cap
- apply externally or in the lower portion of the anal canal only
- apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- for application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus
- thoroughly cleanse dispensing cap after each use and replace cover
- children under 12 years of age: ask a doctor

Other information

store at 20-25°C (68-77°F)

Inactive ingredients

aloe barbadensis leaf extract, butylated hydroxytoluene, cetostearyl alcohol, cetyl esters, cetyl palmitate, distilled water, glycerol monostearate, isopropyl myristate, lanolin, methylparaben, mineral oil, polysorbate 60, propylene glycol, propylparaben, sodium citrate hydrate, stearic acid, tocopherol acetate

DISTRIBUTED BY:

WALLGREEN CO.

200 WILMOT RD.

DEERFIELD, IL 60015

MADE IN KOREA



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| Product Information | | | |
|----------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-1760 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|---|--------------------------------|---------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX) | GLYCERIN | 0.144 mg in 1 g | |
| PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 0.0025 mg in 1 g | |
| PRAMO XINE HYDRO CHLO RIDE (UNII: 88 AYB8 67L5) (PRAMO XINE - UNII: 068 X84E056) | PRAMOXINE HYDROCHLORIDE | 0.01 mg in 1 g | |
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 0.15 mg in 1 g | |

| Ingredient Name LOE VERA LEAF (UNII: ZY81Z83H0 X) UTYLATED HYDRO XYTOLUENE (UNII: 1P9 D0 Z171K) ETOSTEARYL ALCOHOL (UNII: 2DMT128 M1S) ETYL ESTERS WAX (UNII: D072FFP9 GU) ETYL PALMITATE (UNII: 5ZA2S6B08X) VATER (UNII: 059 QF0 KO0 R) LYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4) GOPRO PYL MYRISTATE (UNII: 0 RE8 K4LNJS) | Inactive Ingredients | | |
|---|----------------------|--|--|
| UTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K) ETOSTEARYL ALCO HOL (UNII: 2DMT128 M1S) ETYL ESTERS WAX (UNII: D0 72FFP9 GU) ETYL PALMITATE (UNII: 5ZA2S6 B0 8 X) ATER (UNII: 059 QF0 K00 R) LYCERYL MO NO STEARATE (UNII: 230 O U9 XXE4) | Strength | | |
| ETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) ETYL ESTERS WAX (UNII: D072FFP9GU) ETYL PALMITATE (UNII: 5ZA2S6B08X) ATER (UNII: 059QF0KO0R) LYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | | | |
| ETYL ESTERS WAX (UNII: D072FFP9GU) ETYL PALMITATE (UNII: 5ZA2S6B08X) ATER (UNII: 059QF0KO0R) LYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | | | |
| ETYL PALMITATE (UNII: 5ZA2S6B08X) VATER (UNII: 059QF0KO0R) LYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | | | |
| VATER (UNII: 059QF0KO0R) LYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | | | |
| LYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4) | | | |
| | | | |
| OPROPYL MYRISTATE (LINII: ORF8K4LNIS) | | | |
| OTROTTE MITMOTHER (CAR OREGINALINO) | | | |
| ANOLIN (UNII: 7EV65EAW6H) | | | |
| ETHYLPARABEN (UNII: A2I8C7HI9T) | | | |
| IINERAL O IL (UNII: T5L8T28FGP) | | | |
| OLYSORBATE 60 (UNII: CAL22UVI4M) | | | |
| ROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | |
| ROPYLPARABEN (UNII: Z8IX2SC1OH) | | | |
| RISO DIUM CITRATE DIHYDRATE (UNII: B22547B95K) | | | |
| TEARIC ACID (UNII: 4ELV7Z65AP) | | | |
| LPHATO CO PHERO L ACETATE (UNII: 9E8 X80 D2L0) | | | |

| Packaging | | | |
|--------------------|---|-----------------------------|---------------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:0363-1760-26 | 1 in 1 BOX | 11/08/2016 | |
| 1 | 26 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 | 02/25/2015 | |
| | | | |

Labeler - Walgreen Company (008965063)

Revised: 12/2018 Walgreen Company