TOPCARE HEMORRHOIDAL- cocoa butter, phenylephrine hcl suppository Topco Associates 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.

Topco Associates LLC. Hemorrhoidal Suppositories Drug Facts

Active ingredients (in each suppository)

Cocoa butter 88.44%

Phenylephrine HCl 0.25%

Purposes

Protectant

Vasoconstrictor

Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily relieves burning and 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 rectal 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

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 insertion of this product.
- detach one suppository from the strip; remove the foil wrapper before inserting into the rectum as follows:
- hold suppository with rounded end up
- see illustrations: carefully separate foil tabs by inserting tip of fingernail at end marked "peel down"
- slowly and evenly peel apart (do not tear) foil by pulling tabs down both sides, to expose the suppository
- remove exposed suppository from wrapper
- insert one suppository into the rectum up to 4 times daily, especially at night, in the morning or after each bowel movement
- children under 12 years of age: ask a doctor

Other information

• store at 20-25°C (68-77°F)

Inactive ingredients

methylparaben, propylparaben, topical starch

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

TopCare _® health

COMPARE TO PREPARATION H[®] SUPPOSITORIES ACTIVE INGREDIENTS

NIGHTTIME RELIEF

Hemorrhoidal Suppositories

- Reduces Internal Swelling. Soothes and Protects
- Prompt Soothing Relief from Painful Burning, Itching and Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- **12 SUPPOSITORIES**
- E-Z OPEN WRAPPER



| Drug Facts Active ingredients (in each suppository) Purposes Coca butbr 88.44% Protectant Phenylephrine HCI 0.25% Vasoconstrictor Uses Nasoconstrictor I helps relieve the local it hing and discomfort associated with hemorthoids temporarily relieves burning and shrinks temortroidal is sue I temporarily providesa coafing for relief of anorectal discomforts temporarily provides the inflamed, irritated anorectal surface to help male bowed movements less painful | ■ hold suppository with rounded end up ■ see illus trations: carefully separate bil tabs by inserting tip of finger nail at end marked "peel down" ■ slowly and evenly peel apart(do nottean) foil by pulling tabs down both | Do not use wrapper is Each supposite |
|---|---|---|
| Warnlings For rectal use only Aska doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ difficulty in urination due to enlargement of the prostate gland Aska doctor or pharmacist before use if you are presently taking a | sides, to expose the suppository ■ remove exposed suppository from wrapper ■ insert one suppository into the rectum up to 4 times daily, especially at night, in the moming or after each bowel movement ■ children under 12 years of age: ask a doctor Other Inform ation ■ store at 20-25°C (68-77°F) | Do not use if printed suppository Wrapper is missing or damaged. Each suppository is Individually wrapped |
| prescripf on drug for high blood pressure or depression. When using this product do not exceed the recommended daily dosage unless directed by a doctor | inac tive ingredients menylparaben, propylparaben, opical starch | ositor; haged ly wra |
| Stop use and ask ad oct or if ■ bleeding occurs ■ condition worsens or cbes not improve within 7 days If pregnant or breast-feeding, ask a health professional bebre us a Keepoutof reach of chibbren. If swallowed, get medical help or contact a Poison Control Center right away. (I-800-222-1222) | (Questions or comments? 1-888-423-0139 *This product is not manufactured or distributed by Pfizer, distributor of Preparation H® Suppositories. : 27953 88 € 4 | pped. |
| | This TopCare [®] product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed. | |

TOPCARE HEMORRHOIDAL

cocoa butter, phenylephrine hcl suppository

| Product Information | | | | | | | | |
|---------------------------------------|----------------------------|--------------------|------------------------------|----------|--------------------------------------|--|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | | NDC:3680 | NDC:36800-279 | | | |
| Route of Administration | RECTAL | | | | | | | |
| | | | | | | | | |
| Active Ingredient/Active Moiety | | | | | | | | |
| | | | | | | | | |
| Ingre | edient Name | | Basis of St | renath | Strenath | | | |
| Ingre COCOA BUTTER (UNII: 5120YT10 | | 5120YT1CRR) | Basis of Sti COCOA BUTTER | rength | Strength 2211 mg | | | |
| - | CRR) (COCOA BUTTER - UNII: | | | - | Strength 2211 mg 6.5 mg | | | |

| Inactive Ingredients | | |
|----------------------------------|----------|--|
| Ingredient Name | Strength | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | | |

| ST | STARCH, CORN (UNII: 08232NY3SJ) | | | | | | |
|-----------------------|---------------------------------|-----------------------|---|------------------------|----------------------|--|--|
| | | | | | | | |
| P | roduct Chara | acterist | ics | | | | |
| Color | | | YELLOW (light) | Score | | | |
| Shape | | | | ize | | | |
| Flavor | | | | mprint Code | | | |
| Contains | | | | | | | |
| | | | | | | | |
| Packaging | | | | | | | |
| # | ltem Code | | Package Description | Marketing Star Date | t Marketing Date | | |
| 1 | NDC:36800-279- 62 | 24 in 1 C | ARTON | 11/03/2014 | 03/05/2019 | | |
| 1 | | 1 in 1 BLI Product | STER PACK; Type 0: Not a Combination | | | | |
| 2 | NDC:36800-279- 53 | 12 in 1 C | ARTON | 11/03/2014 | | | |
| 2 | | 1 in 1 BLI Product | STER PACK; Type 0: Not a Combination | | | | |
| | | | | | | | |
| Markating Information | | | | | | | |
| Marketing Information | | | | | | | |
| | • | | | | | | |
| | Marketing Category | Арј | olication Number or Monograph Citation | Marketing Sta Date | rt Marketing Date | | |
| | Marketing | | Citation | | | | |

Labeler - Topco Associates LLC (006935977)

Revised: 9/2022

Topco Associates LLC