

**SIGNATURE CARE HEMORRHOIDAL CREAM (WITH APPLICATOR)- phenylephrine hydrochloride, pramoxine hydrochloride, glycerin, petrolatum cream
BETTER LIVING BRANDS, 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.

Signature Care Hemorrhoidal Cream 2 oz. ZDP 78981

Active ingredients Purpose

Glycerin 14.4%.....Skin protectant

Phenylephrine HCl 0.25%.....Vasconstrictor

Pramoxine HCl 1%.....Local anesthetic

White petrolatum 15%.....Skin 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 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
- difficult in urination due to enlargement of the prostate gland
- diabetes

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

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

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 cream.
- when first opening the tube, peel back foil seal

- apply externally or in the lower portion of the anal canal only
- apply externally 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 room temperature 20-25°C (68-77°F)

Inactive ingredients

.alpha.-tocopherol acetate, aloe vera leaf, anhydrous lanolin, butylated hydroxytoluene, cetostearyl alcohol, cetyl esters wax, cetyl palmitate, glyceryl monostearate, isopropyl myristate, light mineral oil, methylparaben, propylene glycol, propylparaben, purified water, steareth-20, stearic acid, trisodium citrate dihydrate

Distributed by:

Better Living Brands LLC

Made in China

Drug Facts (continued)
 glycol, propylparaben, purified water, steareth-20, stearic acid, trisodium citrate dihydrate
Questions or comments?
 Call 1-888-723-3929
 KEEP OUT OF REACH OF CHILDREN FOR COMPLETE WARNINGS AND PRODUCT INFORMATION. TAMPER EVIDENT DO NOT USE IF CARTON SEAL IS BREACHED OR FOIL UNDER CAP IS BROKEN OR MISSING.

78981-ZDP-BX-R1
 0M-MD-ZDP127-R1

*This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Preparation H® Maximum Strength Pain Relief Cream.
 **Decolorized aloe vera leaf
 DISTRIBUTED BY
 BETTER LIVING BRANDS LLC
 P.O. BOX 99, PLEASANTON, CA 94566-0099
 1-888-723-3929
 www.betterlivingbrandsllc.com
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OUR PROMISE. QUALITY & SATISFACTION GUARANTEED OR YOUR MONEY BACK
 RD 20327 SR670
 Scan here for more information 3 21130 78981 9

Signature Care
 Quality Guaranteed

LOT & EXP.

Hemorrhoidal Cream + Aloe**
 MAXIMUM STRENGTH PAIN RELIEF WITH APPLICATOR
 NDC 21130-981-02

Glycerin 14.4% (Skin protectant)
 Phenylephrine HCl 0.25% (Vasoconstrictor)
 Pramoxine HCl 1% (Local anesthetic)
 White petrolatum 15% (Skin protectant)

- Rapid, Soothing Pain Relief from Painful Burning, Itching and Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves External Discomfort

NET WT 2.0Z (57 g)

Drug Facts
Active ingredients
 Glycerin 14.4%
 Phenylephrine HCl 0.25%
 Pramoxine HCl 1%
 White petrolatum 15%
Purposes
 Skin protectant
 Vasoconstrictor
 Local anesthetic
 Skin 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

Drug Facts (continued)
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

Drug Facts (continued)
 ■ do not put into the rectum by using fingers or any mechanical device or applicator
 ■ Skip use and ask a doctor if
 ■ condition worsens or does not improve within 7 days ■ bleeding occurs ■ an allergic reaction develops
 ■ the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase
 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 cream.
 ■ when first opening the tube, peel back foil seal

Drug Facts (continued)
 ■ apply externally or in the lower portion of the anal canal only
 ■ apply externally 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 room temperature 20-25°C (68-77°F)
Inactive ingredients alpha.-tocopherol acetate, aloe vera leaf, anhydrous lanolin, butylated hydroxytoluene, cetostearyl alcohol, cetyl esters wax, cetyl palmitate, glyceryl monostearate, isopropyl myristate, light mineral oil, methylparaben, propylene glycol, propylparaben, purified water, steareth-20, stearic acid, trisodium citrate dihydrate, white petrolatum 15% (skin protectant)

Maximum Strength Pain Relief Hemorrhoidal Cream + Aloe** With Applicator
 (NDC 21130-981-02)
 Phenylephrine HCl 0.25% (Vasoconstrictor)
 Pramoxine HCl 1% (Local anesthetic)
 White petrolatum 15% (Skin protectant)

SIGNATURE CARE HEMORRHOIDAL CREAM (WITH APPLICATOR)

phenylephrine hydrochloride, pramoxine hydrochloride, glycerin, petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-981
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	144 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
STEARETH-20 (UNII: L0Q8IK9E08)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
WATER (UNII: 059QF0K00R)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
LANOLIN (UNII: 7EV65EAW6H)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-981-02	1 in 1 CARTON	01/04/2021	
1		57 g in 1 TUBE, WITH APPLICATOR; 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	01/04/2021	

Labeler - BETTERLIVING BRANDS, LLC (009137209)

