

EQUALINE HEMORRHOIDAL- glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream

United Natural Foods, Inc. dba UNFI

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.

SuperValu Inc. Hemorrhoidal Cream Drug Facts

Active ingredients

Glycerin 14.4%

Phenylephrine HCl 0.25%

Pramoxine HCl 1%

White petrolatum 15%

Purpose

Protectant

Vasoconstrictor

Local anesthetic

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
- trouble urinating due to an enlarged 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 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 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 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 20°-25°C (68°-77°F)

Inactive ingredients

aloe barbadensis leaf extract, butylated hydroxyanisole, carboxymethylcellulose sodium, cetyl alcohol, citric acid, edetate disodium, glyceryl monostearate, laureth-23, methylparaben, mineral oil, panthenol, propyl gallate, propylparaben, purified water, sodium benzoate, steareth-2, steareth-20, stearyl alcohol, vitamin E, xanthan gum

Questions or comments?

1-855-423-2630

Principal Display Panel

EQUALINE®

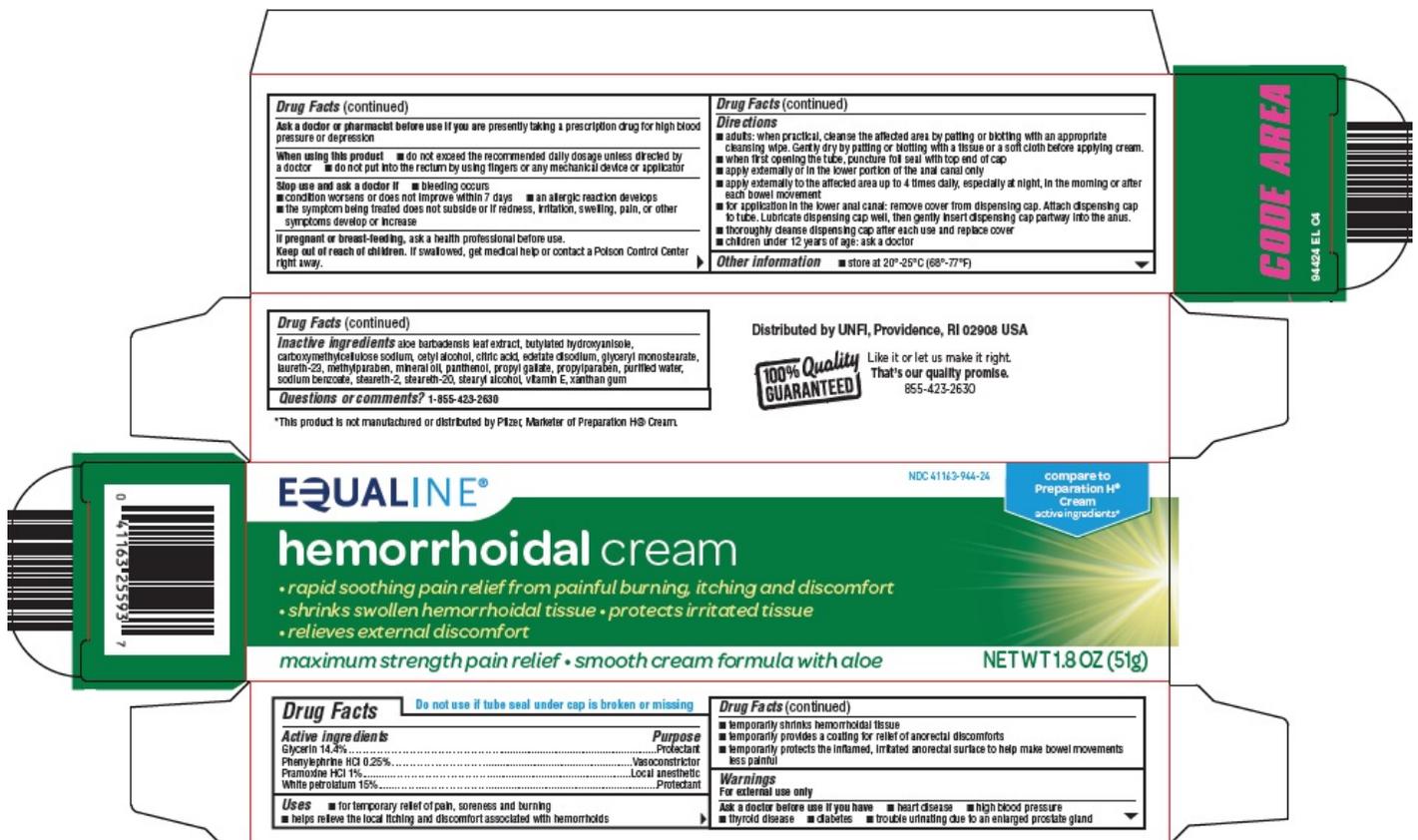
compare to Preparation H® Cream active ingredients

hemorrhoidal cream

- rapid soothing pain relief from painful burning, itching and discomfort
- shrinks swollen hemorrhoidal tissue • protects irritated tissue
- relieves external discomfort

maximum strength pain relief • smooth cream formula with aloe

NET WT 1.8 OZ (51g)



EQUALINE HEMORRHOIDAL

glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41163-944

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	14.4 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LAURETH-23 (UNII: N72LMW566G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PANTHENOL (UNII: WW9CM0O67Z)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-944-24	1 in 1 CARTON	03/28/2008	

1	51 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	03/28/2008	

Labeler - United Natural Foods, Inc. dba UNFI (943556183)

Revised: 8/2023

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