

NATUREPLEX HEMORRHOIDAL- witch hazel and phenylephrine hydrochloride gel
Natureplex 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.

Natureplex™
Hemorrhoidal Cooling Gel

Drug Facts

<i>Active ingredients</i>	<i>Purposes</i>
Phenylephrine HCl 0.25%	Hemorrhoidal (anorectal) Gel
Hamamelis Virginiana (witch hazel) 50%	Hemorrhoidal (anorectal) Gel

Uses

- temporarily relieves anorectal itching and discomfort associated with hemorrhoids or anorectal disorders
- temporarily reduces the swelling associated with irritation in hemorrhoids and other anorectal disorders
- temporarily shrinks hemorrhoidal tissue
- aids in protecting irritated anorectal areas
- temporary relief of burning

Warnings

For external use only.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty urinating due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are 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
- the condition worsens or does not improve within 7 days. These may be signs of a serious condition.

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: 800-222-1222.

Directions

Adults:

- when practical, cleanse affected area by patting or blotting with appropriate cleansing wipe. Gently dry by patting or blotting with tissue or soft cloth before applying gel.
- apply externally to affected area up to 4 times daily or after each bowel movement
- **Children under 12 years:** ask a doctor

Other information

- store at 15 to 30°C (59 to 86°F)
- close cap tightly after use
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

Inactive ingredients

aloe barbadensis leaf juice, benzophenone-4, disodium EDTA, hydroxyethylcellulose, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate

Questions or comments?

866-323-0107 or www.natureplex.com

PRINCIPAL DISPLAY PANEL - 25.5 g Tube Box

NDC 67234-024-01

Natureplex™

Anesthetic

HEMORRHOIDAL

Cooling Gel With Soothing Aloe

NET WT. 0.9 Oz.(25.5g)

Fast Cooling Relief

NATUREPLEX HEMORRHOIDAL

witch hazel and phenylephrine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-024
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 10 1I4J0 U34) (WITCH HAZEL - UNII:10 1I4J0 U34)	WITCH HAZEL	0.5 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59 TNSJ) (PHENYLEPHRINE - UNII:1WS29 7W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.0025 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450 LGA)	
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	
BENZOPHENONE (UNII: 70 1M4TTV9 O)	
HYDROXYETHYL CELLULOSE (280 MPa.s at 2 %) (UNII: 12VCE9HR9 E)	
EDETATE DISODIUM (UNII: 7FLD9 1C86 K)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PROPYLENE GLYCOL (UNII: 6DC9 Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059 QF0 KO0 R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-024-01	1 in 1 BOX	03/18/2014	
1		25 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	03/18/2014	

Labeler - Natureplex LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-024)