GNP MEDICATED WIPES - witch hazel solution Amerisource Bergen

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.

Drug Facts

Active ingredient

Purpose

Witch Hazel, 50% v/v.....Astringent

Uses For temporary relief of local discomfort itching, burning, and irritation associated with hemorrhoids

Warnings For external use only. Avoid contact with eyes.

Consult a doctor

- if condition worsens or does not improve within 7 days
- in case of bleeding
- before exceeding the recommended dosage

Do not put this product into rectum using fingers or any mechanical device or applicator.

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 and children 12 years and older: up to 6 times daily or after each bowel movement
- Children under 12: consult a doctor
- When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- Gently dry by patting or blotting with toilet tissue or soft cloth before each application of this product. Gently apply to the affected area by patting and discard. Apply to the affected area up to 6 times daily or after each bowel movement.

Other information Store at room temperature: 15° - 30 °C (59° - 86°F)

Inactive ingredient aloe barbadensis gel, citric acid, diazolidinyl urea, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate

Distributed By

Amerisource Bergen

1300 Morris Drive

Chesterbrook, PA 19067

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GNP MEDICATED W	TIPES				
vitch hazel solution					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:46122-055	
Route of Administration	TOPICAL, RECTAL				
Active Ingredient/Active I	Moiety				
Ingredient Name Basis of Strengtl					Strength
WITCH HAZEL (UNII: 10 1I4J0 U34) (WITCH HAZEL - UNII:10 1I4J0 U34) WITCH HAZEL					0.5 mg in 1 mg
Inactive Ingredients					
		Strength			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				

DIAZOLIDINYL UREA ((UNII: H5RIZ3MPW4)							
GLYCERIN (UNII: PDC6A3C0OX)								
METHYLPARABEN (UNII: A2I8C7HI9T)								
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)								
PROPYLPARABEN (UN	PROPYLPARABEN (UNII: Z8IX2SC1OH)							
WATER (UNII: 059QF0K00R)								
SODIUM CITRATE (UNII: 1Q73Q2JULR)								
Packaging								
# Item Code	Package Description	Marketing Start Date		Marketing End Date				
1 NDC:46122-055-67	48 in 1 POUCH							
1	0.5 mg in 1 APPLICATOR							
Marketing Info	rmation							
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date			
OTC monograph final	part346		06/30/2013		Marketing End Date			
o re monographi imar	parto-to		00/30/2015					

Labeler - Amerisource Bergen (007914906)

Revised: 6/2013

Amerisource Bergen