

HARMON FACE VALUES MEDICATED- witch hazel solution
Harmon Stores Inc.

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%.....	Astringent

Uses

Temporarily relieves these external symptoms associated with hemorrhoids: itching, burning, and irritation

Warnings For external use only. Avoid contact with eyes.

When using this product

- Do not exceed the recommended daily dosage unless directed by a doctor - Do not put directly in rectum by using fingers or any mechanical device

Stop use and ask a doctor if

- Rectal bleeding occurs
- condition worsens or does not improve within 7 days

Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- As hemorrhoidal treatment for adults:
- When practical clean 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 applying
- Gently apply to the affected area by patting and then discard
- Can be used up to six times daily or after each bowel movement
- **Children under 12 years of age: ask a doctor**

Other Information: store at 20° to 25°C (68° to 77°F)

Inactive Ingredients: alcohol, citric acid, diazolidinyl urea glycerin, methylparaben, propylene glycol, propylparaben, sodium citrate, water

Distributed by: Harmon Stores, Inc.

650 Liberty Ave., Union, NJ 07083 USA

Made in China



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-803
Route of Administration	TOPICAL, RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	WITCH HAZEL	.5 mg in 1 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-803-76	100 in 1 JAR		
1		2.5 mg in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	08/23/2013	

Labeler - Harmon Stores Inc. (804085293)

