FAMILY CARE MEDICATED HEMORRHOIDAL - witch hazel cloth UNITED EXCHANGE CORPORATION

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

Uses

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

Warnings

For external use only.

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 59° to 77°F

Inactive ingredient:

water, glycerin, alcohol, propylene glycol, sodium citrate, diazolidinyl urea, citric acid, methylparaben, and propylparaben

Distributed by:

United Exchange Corp.

17211 Valley View Ave.

Cerritos, CA 90703 USA

Made in China



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FAMILY CARE MEDICATED HEMORRHOIDAL

witch hazel cloth

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-802
Route of Administration	TOPICAL		

ı	Active Ingredient/Active Moiety		
ı	Ingredient Name	Basis of Strength	Strength
ı	WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	WITCH HAZEL	5 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q 16 7 V 3)	
SO DIUM CITRATE (UNII: 1Q73Q2JULR)	

DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-802-09	8 in 1 CARTON		
1		1 in 1 POUCH		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part346	07/20/2011		

Labeler - UNITED EXCHANGE CORPORATION (840130579)

Registrant - UNITED EXCHANGE CORPORATION (840130579)

Establishment			
Name	Address	ID/FEI	Business Operations
AMERICAN HYGIENICS CORPORATION		545198454	manufacture

Revised: 7/2011 UNITED EXCHANGE CORPORATION