PREMIER VALUE MEDICATED PADS - witch hazel solution
CHAIN DRUG CONSORTIUM, 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.

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 20º to 25ºC (68º to 77ºF)

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

Other Uses

For vaginal care- cleanse the area by gently wiping, patting or blotting with pad and discard. Repeat as needed.

Distributed by:

Geiss, Destin and Dunn Inc.

Peachtree City, GA 30269

www.valuelabels.com

Made in China

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PREMIER VALUE MEDICATED PADS

witch hazel solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-410
Route of Administration	RECTAL, TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 101I4J0U34) (WITCH HAZEL - UNII:101I4J0U34)	WITCH HAZEL	0.5 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-410-91	100 in 1 JAR		
1		2.5 mL in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/01/2011	

Labeler - CHAIN DRUG CONSORTIUM, LLC (101668460)

Registrant - UNITED EXCHANGE CORP. (840130579)

Establishment

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

Revised: 6/2011 CHAIN DRUG CONSORTIUM, LLC