

WESTERN FAMILY HYGIENIC CLEANSING- witch hazel cloth

Western Family Foods, 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.

Active ingredient	Purpose
Witch Hazel 50%.....	Astringent

Uses

Temporarily relieves the 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:

Western Family Foods, Inc.

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Portland, OR 97208 USA

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Made in China



WESTERN FAMILY HYGIENIC CLEANSING

witch hazel cloth

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-776
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 g

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958 V90M)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
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:55312-776-00	100 in 1 JAR; 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	07/10/2015	

Labeler - Western Family Foods, Inc (192166072)

