

TOPCARE MEDICATED CLEANSING PADS - witch hazel solution
TOPCO ASSOCIATES 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 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 TOPCO ASSOCIATES

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MADE IN CHINA



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TOPCARE MEDICATED CLEANSING PADS

with hazel solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-068
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	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: 059QF0K00R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-068-10	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	03/01/2012	

