MEDICATED WIPES - witch hazel solution Triad Group

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

Witch Hazel 50% v/v

PURPOSE

Astringent

USE

For temporary relief of local discomfort, burning, and irritation associated with hemorrhoids

WARNINGS

For external use only. Avoid contact with eyes.

Consult a doctor

- if condition worsens or does not improve within 7 days
- in case of bleeding
- before exceeding the recommended dosage

Do not

put this product into rectum using fingers or any mechanical device or applicator

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

Up to 6 times daily or after each bowel movement	
 Consult a doctor	

- When practical, cleanse 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 each application of this

product. Gently apply to the affected area by patting and then discard. Apply to the affected area up to 6 times daily or after each bowel movement.

OTHER INFORMATION

- Store at room temperature: 15°- 30° C (59° 86° F)
- For best results, flush only one wipe at a time

OTHER USES

- **for vaginal care** cleanse the area by gently wiping, patting or blotting with pad and discard. Repeat as needed.
- **for use as a moist compress** if necessary, first cleanse the area as previously described. Fold wipe to desired size and place in contact with tissue for a soothing and cooling effect. Leave in place for up to 15 minutes and repeat as needed.

INACTIVE INGREDIENTS

aloe barbadensis gel, citric acid, diazolidinyl urea, glycerin, methylparaben, propylene glycol, propylparaben, sodium citrate, water

PACKAGE INFORMATION - LABEL

NDC 50730-7993-1 Compare to Preparation H® active ingredient* CAREONE®

pre-moistened **MEDICATED WIPES**

MEDICATED WIFES

HEMORRHOIDAL WIPES WITH WITCH HAZEL WITH ALOE

Comforts, Soothes Cools Irritated Tissue Flushable 48 WIPES

Distributed by: American Sales Company 4201 Walden Avenue Lancaster, NY, 14086

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Quality Guaranteed or your money back.

*This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark PREPARATION H®.





MEDICATED WIPES

witch hazel solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50730-7993
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
witch hazel (UNII: 101I4J0U34) (witch hazel - UNII:101I4J0U34)	witch hazel	0.50 mL in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
aloe vera leaf (UNII: ZY8 1Z8 3H0 X)			
citric acid monohydrate (UNII: 2968PHW8QP)			
diazolidinylurea (UNII: H5RIZ3MPW4)			
glycerin (UNII: PDC6 A3C0 OX)			
methylparaben (UNII: A2I8C7HI9T)			
propylene glycol (UNII: 6DC9Q167V3)			
propylparaben (UNII: Z8IX2SC1OH)			
sodium citrate (UNII: 1Q73Q2JULR)			
water (UNII: 059QF0KO0R)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50730-7993-1	48 in 1 PACKAGE		
1		4.5 mL in 1 APPLICATOR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	04/13/2010	

Labeler - Triad Group (050259597)

Revised: 4/2010 Triad Group