

LEADER MEDICATED WIPES - witch hazel solution
Cardinal Health

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

Adults and children 12 years and older	Up to 6 times daily or after each bowel movement
Children under 12	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 37205-625-67

LEADER®

Compare to Preparation H® active ingredient*

PRE-MOISTENED

Medicated Wipes

Hemorrhoidal Wipes with Witch Hazel

- Cools, soothes and provides temporary relief of itching, burning and irritation
- For use with hemorrhoids and for vaginal care
- Convenient, easy to use
- Flushable

with Aloe

48 Wipes

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017

CIN 4246294 www.myleader.com 1-800-200-6313

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

FRONT PANEL

Hard Top Cover Area

ANGLED AREA

ANGLED AREA

Drug Facts		Drug Facts (continued)		Drug Facts (continued)	
Active ingredient Witch Hazel, 50% w/v	Purpose Astringent	Consult a doctor • if condition worsens or does not improve within 7 days • in case of bleeding • before exceeding the recommended dosage		Directions	
Use For temporary relief of local discomfort, itching, burning, and irritation associated with hemorrhoids		Do not put this product into rectum using fingers or any mechanical device or applicator.		Adults and children 12 years and older	Up to 6 times daily or after each bowel movement
Warnings For external use only. Avoid contact with eyes.		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		Children under 12	Consult a doctor

SIDE PANEL

Drug Facts (continued)	Drug Facts (continued)	Other Uses
<ul style="list-style-type: none"> 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 discard. Apply to the affected area up to 6 times daily or after each bowel movement. 	Other information <ul style="list-style-type: none"> Store at room temperature: 15° - 30° C (59° - 86° F) For best results, flush only one wipe at a time. 	<ul style="list-style-type: none"> 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.

BACK PANEL

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

Rev. A1009

NDC 37205-625-67



UPC-A FPO

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Compare to Preparation H
active ingredient*

with Aloe



Rev. A1209

LEADER MEDICATED WIPES

witch hazel solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-625
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
witch hazel (UNII: 10 1I4J0U34) (witch hazel - UNII:10 1I4J0U34)	witch hazel	0.50 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY8 1Z83H0X)	
citric acid monohydrate (UNII: 2968PHW8QP)	
diazolidinylurea (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:37205-625-67	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 - Cardinal Health (097537435)