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

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 37205-625-67

LEADER®

Compare to Preparation H® active ingredient*

PRE-MOISTENED Medicated Wipes

Hemorrhoidal Wipes with Witch Hazel

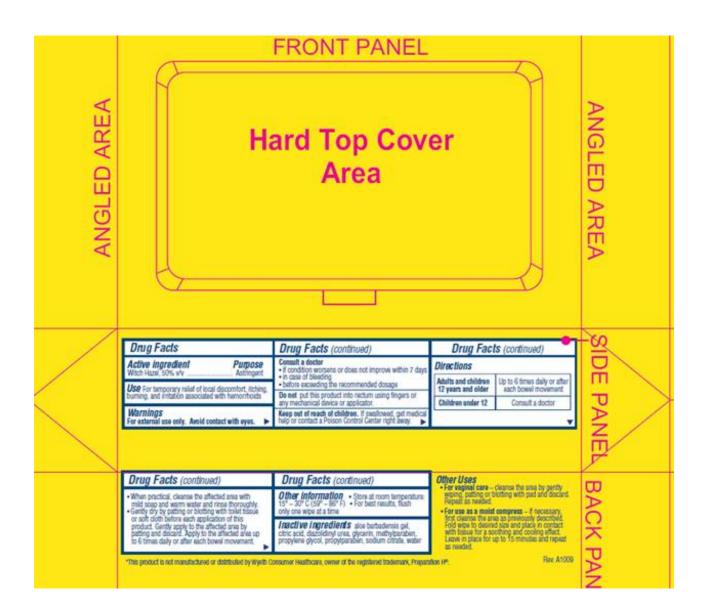
- Cools, soothes and provides temporary relief of itching, burning and irritation
- For use with hemorrhoids and for vaginal care
- Convenient, easy to use
- Flushable

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®.





LEADER MEDICATED WIPES

witch hazel solution

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F	Product Information	1							
P	Product Type		HUMAN OTC DRUG	Ite m C	Item Code (Source)		NDC:37205-625		
F	Route of Administration	1	TOPICAL						
Active Ingredient/Active Moiety									
Ingredient Name Basis of Streng						ength	Strength		
witch hazel (UNII: 101I4J0U34) (witch hazel - UNII:101I4J0U34) witch hazel							0.50 mL in 1 mL		
Inactive Ingredients									
			Strength						
a	loe vera leaf (UNII: ZY81								
ci	itric acid monohydrate (
d	iazolidinylurea (UNII: H								
g	lycerin (UNII: PDC6A3C0								
methylparaben (UNII: A2I8C7HI9T)									
propylene glycol (UNII: 6DC9Q167V3)									
p	ropylparaben (UNII: Z8E								
s	odium citrate (UNII: 1Q73								
water (UNII: 059QF0KO0R)									
P	ackaging								
#	Item Code	Pacl	kage Description	Marketii	ng Start Date	Ma	rketing End Date		
1	NDC:37205-625-67	48 in 1 PA	CKAGE						
1		4.5 mL in	1 APPLICATOR						
Marketing Information									
					Marketing Star	t Date	Marketing End Date		
	OTC monograph final part346			r - Crauton	04/13/2010				
_	P								

Labeler - Cardinal Health (097537435)