PREPARATION H MEDICATED WIPES- witch hazel cloth Wyeth Consumer Healthcare 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.

Preparation H Medicated Wipes (witch hazel)

DRUG FACTS

ACTIVE INGREDIENT

Witch hazel 50.0%

PURPOSE

Astringent

USES

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporary relief of irritation and burning
- aids in protecting irritated anorectal areas

WARNINGS

For external use only

When using this product

- do not exceed the recommended daily dosage unless directed by a doctor
- do not put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- 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

- open the lid on the top of the wipes pouch
- peel back wipes seal, remove completely and discard
- grab the top wipe at the edge of the center fold and pull out of pouch
- close lid after each use to retain moisture
- adults: unfold wipe and cleanse the area by gently wiping, patting or blotting. If necessary, repeat
 until all matter is removed from the area
- use up to 6 times daily or after each bowel movement and before applying topical hemorrhoidal treatments, and then discard
- children under 12 years of age: consult a doctor

OTHER INFORMATION

- for best results, flush only one or two wipes at a time
- store at 20-25°C (68-77°F)

INACTIVE INGREDIENTS

aloe barbadensis leaf juice, anhydrous citric acid, capryl/capramidopropyl betaine, diazolidinyl urea, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate

QUESTIONS OR COMMENTS?

Call weekdays 9 AM to 5 PM EST at 1-800-99PrepH or 1-800-997-7374

PRODUCT PACKAGING

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available.

PREPARATION H Medicated Wipes

Hemorrhoidal Wipes with Witch Hazel

MAXIMUM STRENGTH FORMULA

Gentle, Everyday Cleansing To Reduce Irritation

48 Medicated Wipes With Aloe

Cools, Soothes and Comforts

Convenient, Easy to Use

For Hemorrhoidal and Vaginal Care

Flushable and Septic Safe

6 x 5 in. (15.2 x 12.7 cm)

For most recent product information, visit www.preparationh.com

Marketed By Wyeth Consumer Healthcare

Madison, NJ 07940 USA

Made in USA © 2009 Wyeth

10 Wipes Individually Wrapped

Each wipe is enclosed in a sealed foil pouch. Do not use if the pouch is broken or torn.

Other Uses

- **for vaginal care** cleanse the area by gently wiping, patting or blotting. Repeat as needed.
- **for use as a moist compress** if necessary, first cleanse the area as previously described. Fold new 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.

MAXIMUM STRENGTH FORMULA

PREPARATION

Hemorrhoidal Wipes with Witch Hazel

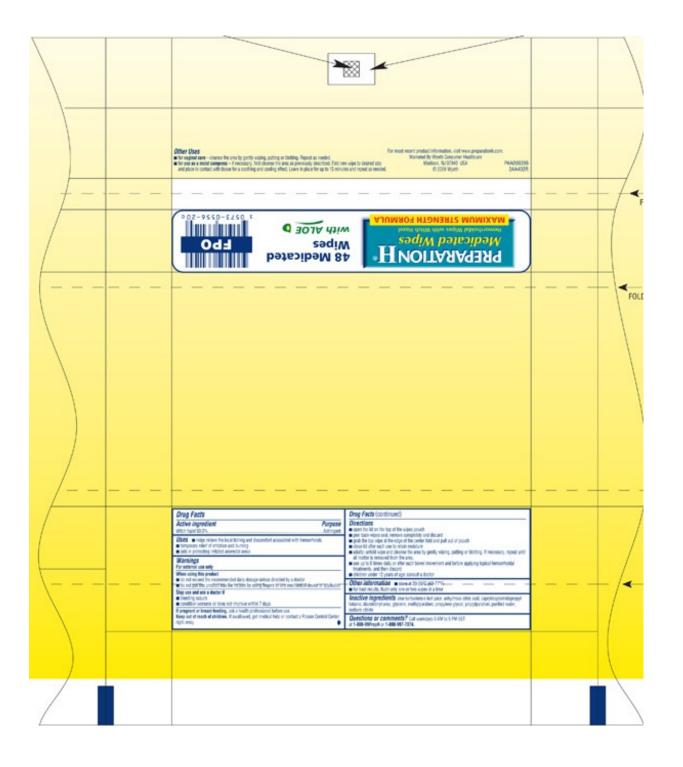
Gentle, Everyday Cleansing To Reduce Irritation

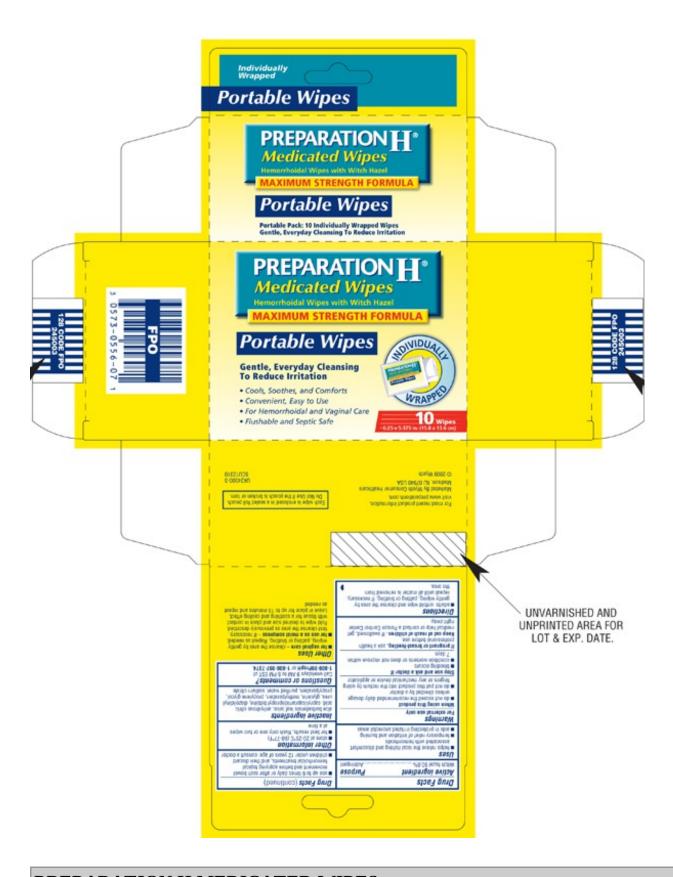
- Cools, Soothes, and Comforts
- Convenient, Easy to Use
- For Hemorrhoidal and Vaginal Care
 Flushable and Septic Safe

48 Medicated Wipes with ALOE 6x5 in. (15.2 x 12.7 cm)



20A592SLI





PREPARATION H MEDICATED WIPES

witch hazel cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-0556	
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	5 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
CAPRYL/CAPRAMIDO PRO PYL BETAINE (UNII: 231H3ZT9 NE)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
GLYCERIN (UNII: PDC6A3C0OX)		
METHYLPARABEN (UNII: A2I8 C7HI9 T)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
WATER (UNII: 059QF0KO0R)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0573-0556-07	10 in 1 CARTON	02/02/2004		
1		1 in 1 PACKET; Type 0: Not a Combination Product			
2	NDC:0573-0556-96	2 in 1 CARTON	02/02/2004		
2	NDC:0573-0556-20	48 in 1 POUCH; Type 0: Not a Combination Product			
3	NDC:0573-0556-20	48 in 1 POUCH; Type 0: Not a Combination Product	02/02/2004		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part346	02/02/2004		

Labeler - Wyeth Consumer Healthcare LLC (828831730)

Revised: 12/2018 Wyeth Consumer Healthcare LLC