

HARMON FACE VALUES MEDICATED WIPES - witch hazel cloth
HARMON STORES INC.

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% v/v.....	Astringent

Uses

For temporary relief of local discomfort itching, 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.

If pregnant or breast-feeding, ask a health professional before use.

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 discard. Apply to the affected area up to 6 times daily or after each bowel movement.

Store at room temperature: 15°-30°C (59°-86°F)

Inactive ingredients

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

Distributed by

Harmon Stores Inc.

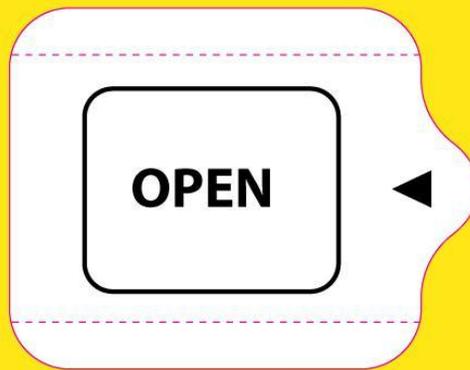
550 Liberty Ave.

Union, NJ 07083

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Drug Facts	Drug Facts (continued)	Drug Facts (continued)
Active ingredient Witch Hazel, 50% v/v	Purpose Astringent	<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.
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Directions <ul style="list-style-type: none"> Adults and children 12 years and older Children under 12 	Directions <ul style="list-style-type: none"> Up to 6 times daily or after each bowel movement Consult a doctor 	Other information Store at room temperature: 15°–30° C (59°–86° F)
Warnings Consult a doctor <ul style="list-style-type: none"> if condition worsens or does not improve within 7 days in case of bleeding • before exceeding the recommended dosage 		Inactive ingredients aloe barbadensis gel, citric acid, diazolidinyl urea, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate

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

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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.

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HARMON FACE VALUES MEDICATED WIPES

witch hazel cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-802
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-802-48	48 in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/31/2012	

Labeler - HARMON STORES INC. (804085293)