

**QUALITY CHOICE MEDICATED WIPES- witch hazel cloth**  
**American Hygienics Corporation**

*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.*

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**QUALITY CHOICE Medicated Wipes**

***Drug Facts***

***Active ingredient***

Witch hazel 50%

***Purpose***

Anorectal/Astringent

***Uses***

- temporarily relieves the local itching and discomfort associated with hemorrhoids
- aids in protecting irritated anorectal areas
- temporarily relieves irritation and burning

***Warnings***

**For external use only**

**When using this product**

- do not use more than directed unless told to do so by a doctor
- do not put directly in the rectum by using fingers or any mechanical device or applicator

**Stop use and ask a doctor if**

- rectal bleeding occurs
- condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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. **Do Not Flush.**
- children under 12 years of age: consult a doctor

### ***Other information***

- store at room temperature 20-25°C (68-77°F) • protect from excessive heat

### ***Inactive ingredients***

alcohol, aloe vera leaf, citric acid, diazolidinyl urea, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate

### **Compare to the Active Ingredient in PREPARATION H®**

#### **Hemorrhoidal/Vaginal Wipes with Witch Hazel**

Soothes & Comforts Irritated Areas

Pre-moistened Cooling Wipes

Distributed by C.D.M.A., Inc. ©

43157 W 9 Mile Rd

Novi, MI 48375

[www.qualitychoice.com](http://www.qualitychoice.com)

Questions: 800-935-2362

#### **Other Uses:**

- **For external 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. Fold new wipe to desired size and place in contact with irritated area for a soothing and cooling effect. Leave in place for up to 15 minutes and repeat as needed.

#### **TAMPER EVIDENT: DO NOT USE IF POUCH IS OPEN OR DAMAGED.**

\*This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Preparation H® Medicated Wipes.

\*\*Decolorized. Prop 65.

Made in China

### **Packaging**





## DRUG FACTS LABEL

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<b>Uses</b> ■ temporarily relieves the local itching and discomfort associated with hemorrhoids ■ aids in protecting irritated anorectal areas ■ temporarily relieves irritation and burning		<b>Directions</b> ■ 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. <b>Do Not Flush.</b> ■ children under 12 years of age: consult a doctor	
<b>Warnings</b> For external use only <b>When using this product</b> ■ do not use more than directed unless told to do so by a doctor ■ do not put directly in the rectum by using fingers or any mechanical device or applicator <b>Stop use and ask a doctor if</b> ■ rectal bleeding occurs ■ condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.		<b>Other information</b> ■ store at room temperature 20-25°C (68-77°F) ■ protect from excessive heat <b>Inactive ingredients</b> alcohol, aloe vera leaf, citric acid, diazolidinyl urea, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate	

**QUALITY CHOICE MEDICATED WIPES**

witch hazel cloth

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:15533-396
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
WITCH HAZEL (UNII: 101I4J0U34) (WTCH HAZEL - UNII:101I4J0U34)	WTCH HAZEL	50 g in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15533-396-01	48 in 1 POUCH	07/28/2021	
1		4.68 mL in 1 PACKAGE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part346	07/28/2021	

**Labeler** - American Hygienics Corporation (545198454)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
American Hygienics Corporation		545198454	manufacture(15533-396)

