QUALITY CHOICE MEDICATED PADS- 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.

QUALITY CHOICE Medicated Pads

Drug Facts

Active Ingredient

Witch Hazel, 50%

Purpose

Astringent

Use

Temporarily relieves these external symptoms associated with hemorrhoids:

• itching • burning • irritation

Warnings

For external use only. Avoid contact with eyes.

When using this product • do not exceed the recommended daily dosage unless directed by a doctor. • do not put directly into rectum by using fingers or any mechanical device.

Stop use and ask a doctor if • Rectal 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:

As hemorrhoidal treatment for adults:

- When practical, clean 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 applying.
- Gently apply to the affected area by patting and then discard.
- Can be used up to six times daily or after each bowel movement.

Children under 12 years of age: ask a doctor

Other Information

Store at 20° to 25°C (68° to 77°F)

Inactive Ingredients

alcohol, citric acid, diazolidinyl urea, glycerin, methylparaben, propylene glycol, propylparaben, sodium citrate, water

* Compare to the Active Ingredient in TUCKS® Medicated pads

Hemorrhoidal/Vaginal pads with Witch Hazel

Pre-moistened Pads Provide Temporary Relief of Burning, Itching and Local Discomfort Associated with Hemorrhoids

Other Uses For vaginal care - Cleanse the area by gently wiping, patting or blotting with pad and discard. Repeat as needed.

FOR YOUR PROTECTION, JAR IS SEALED. IF SEAL IS BROKEN OR MISSING, DO NOT USE.

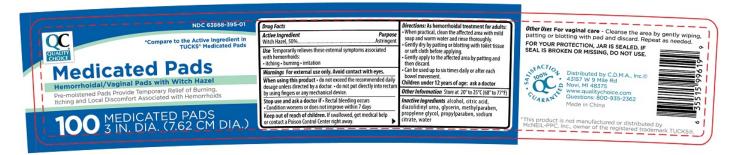
• SATISFACTION • GUARANTEED 100% QC

Distributed by C.D.M.A., Inc.© 43157 W 9 Mile Rd Novi, MI 48375 www.qualitychoice.com Ouestions: 800-935-2362

Made in China

*This product is not manufactured or distributed by McNEIL-PPC, Inc., owner of the registered trademark TUCKS®.

Packaging



DRUG FACTS LABEL

Drug Facts	Directions: As hemorrhoidal treatment for adults:		
Active Ingredient Purpose Witch Hazel, 50%Astringent	 When practical, clean the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue 		
Use Temporarily relieves these external symptoms associated with hemorrhoids: • itching • burning • irritation	or soft cloth before applying. • Gently apply to the affected area by patting and then discard. • Can be used up to six times daily or after each bowel movement. Children under 12 years of age: ask a doctor		
Warnings For external use only. Avoid contact with eyes.			
When using this product • do not exceed the recommended daily dosage unless directed by a doctor. • do not put directly into rectum			
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QUALITY CHOICE MEDICATED PADS

witch hazel cloth

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:15533-395

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
WITCH HAZEL (UNII: 10114)0U34) (WTCH HAZEL - UNII:10114)0U34)
WTCH HAZEL
0.0086 q

Inactive Ingredients Ingredient Name Strength ALCOHOL (UNII: 3K9958V90M) CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4) GLYCERIN (UNII: PDC6A3C0OX) METHYLPARABEN (UNII: A2I8C7HI9T) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) PROPYLPARABEN (UNII: Z8IX2SC10H)

SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)

WATER (UNII: 059QF0KO0R)

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:15533-395- 01	100 in 1 JAR; Type 0: Not a Combination Product	05/12/2021			

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	TC monograph final part346						

Labeler - American Hygienics Corporation (545198454)

Establishment						
Name	Address	ID/FEI	Business Operations			
American Hygienics Corporation		545198454	manufacture(15533-395)			

Revised: 7/2021 American Hygienics Corporation