

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

Questions: 800-935-2362

Made in China

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

Packaging

NDC 63868-395-01

QC QUALITY CHOICE

*Compare to the Active Ingredient in TUCKS® Medicated Pads

Medicated Pads

Hemorrhoidal/Vaginal Pads with Witch Hazel

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

100 MEDICATED PADS
3 IN. DIA. (7.62 CM DIA.)

| Drug Facts | Purpose |
|---|-------------------|
| Active Ingredient Witch hazel, 50%..... | Astringent |
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DRUG FACTS LABEL

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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 | Strength |
|---|-------------------|----------|
| WITCH HAZEL (UNII: 101I4J0U34) (WTCH HAZEL - UNII:101I4J0U34) | WTCH HAZEL | 0.0086 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| 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 | part346 | 05/12/2021 | |

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