

HEMORRHOIDAL HYGIENE PADS- witch hazel solution

Geritrex, 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.

Hemorrhoidal Hygiene pads

Drug Facts

Witch Hazel 50%

Purpose: Hemorrhoidal Astringent

Uses

For temporary relief of local discomfort, burning and irritation associated with Hemorrhoids

Directions

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 a soft cloth before applying
- Apply externally to the affected area up to 6 times daily or after each bowel movement
- After application, discard pad

Children under 12 years of age: consult a doctor

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

- For External Use Only
- Avoid contact with the 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 the rectum using fingers or any mechanical device.

Other Ingredient

Alcohol, Citric Acid,
Deionized Water, DMDM Hydantoin,
Glycerin, Sodium Citrate.

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

If swallowed, contact the Poison Control Center immediately.



NDC# 54162-004-01

Hemorrhoidal Hygiene Pads
With Witch Hazel

Cooling & soothing
For hemorrhoids & vaginal care

100 PADS

Compatible to active ingredients in Tucks® McNeil-PPC

For immediate relief from itching, burning and irritation

Other uses:
Hygiene Wipe: for everyday personal hygiene on outer rectal and vaginal area.
A Moist Compress: for inflamed tissue, especially for relieving discomfort from rectal or vaginal surgery.

No Animal Testing, Latex Free

**Drug Facts**

Active Ingredient: Witch Hazel 50%
Purpose: Hemorrhoidal Astringent

Uses: For temporary relief of local discomfort, burning and irritation associated with Hemorrhoids.

Warnings:
• **For External Use Only**
• Avoid contact with the 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 the rectum using fingers or any mechanical device.
Keep out of reach of children. If swallowed, get medical attention or contact the Poison Control Center immediately.

Directions:
• 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 a soft cloth before applying.
• Apply externally to the affected area up to 6 times daily or after each bowel movement.
• After application, discard pad.
Children under 12 years of age: consult a doctor.

Other Information:
Store at room temperature 15°-30°C (59°-86°F)
If adverse effects call 1-800-736-3437.

Other Ingredients: Alcohol, Citric Acid, Deionized Water, DMDM Hydantoin, Glycerin, Methyl and Propyl Parabens, Sodium Citrate.

HEMORRHOIDAL HYGIENE PADS

witch hazel solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-004
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 10 1I4J0 U34) (WITCH HAZEL - UNII:10 1I4J0 U34)	WITCH HAZEL	50 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958 V90M)	
ACETYLTRIBUTYL CITRATE (UNII: 0 ZBX0 N59 RZ)	
WATER (UNII: 059 QF0 K00 R)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
DMDM HYDANTOIN (UNII: BYR0546 TOW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-004-25	45 mL in 1 JAR; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/31/2015	

Labeler - Geritrex, LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex, LLC		112796248	manufacture(54162-004)

Revised: 12/2018

Geritrex, LLC