LEADER MEDICATED PADS - witch hazel solution CARDINAL HEALTH

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%Astringent

Uses

Temporarily relieves these external symptoms associated with hemorrhoids: itching, burning, and 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 in 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

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

CIN 1491687

www.myleader.com

Made in China



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LEADER MEDICATED PADS

witch hazel solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:37205-739

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthWITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII: 10 114J0 U34)WITCH HAZEL0.5 mL in 1 mL

Inactive Ingredients Ingredient Name Strength ALCOHOL (UNII: 3K9958 V90 M) CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) GLYCERIN (UNII: PDC6 A3C0 O X) METHYLPARABEN (UNII: A2I8 C7HI9 T) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) PROPYLPARABEN (UNII: 28 IX2SC10H) SODIUM CITRATE (UNII: 1Q73Q2JULR) WATER (UNII: 059QF0 KO0 R)

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:37205-739-78	100 in 1 JAR				
1		2.5 mL in 1 APPLICATOR				

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part346	0 4/0 1/20 12					

Labeler - CARDINAL HEALTH (097537435)

Revised: 4/2012 CARDINAL HEALTH