

SHOPKO MEDICATED COOLING- witch hazel swab
Shopko Stores Operating Co., 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.

SHOPKO Medicated Cooling Pads

Active Ingredient

Witch hazel 50%

Purpose

Astringent

Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporary relief of irritation and burning.
- aids in protecting irritated anorectal areas.

Warnings

For external use only.

When using this product

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

Stop use and ask a doctor if

- 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.(1-800-222-1222)

If pregnant or breast-feeding

Ask a health professional before use

Directions

- adult: 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 hemorrhoidal treatments, and then discard
- children under 12 years of age: consult a doctor

- Dispose of pad in trash after use. Do not flush

Other information

- store at room temperature 15-30°C (59-86°F)
- for vaginal care - cleanse the area by gently wiping, patting, or blotting. Repeat as needed.
- for use as moist compress - if necessary, first cleanse the area as previously described. Fold wipe to desired size and place in contact with tissue for a soothing and cooling effect. Leave in place for 15 minutes and repeat as needed.

Inactive Ingredients

Alcohol, Aloe, citric acid, Decyl Glucoside, Glycerin, Phenoxyethanol, Potassium Sorbate, Propylene Glycol, Sodium Benzoate, Water.

Principal Display Panel

SHOPKO

Compared to the active ingredients in Tucks*

Medicated Cooling Pads

hemorrhoidal pads with witch hazel

- Fast, soothing relief from Irritation and burning
- For hemorrhoidal and vaginal care

100 pads 3.0 sq. in. (7.6 sq. cm)



SHOPKO MEDICATED COOLING

witch hazel swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:370 12-211
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	WITCH HAZEL	50 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:370 12-211-00	100 in 1 PACKAGE	05/09/2017	
1		2.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	05/09/2017	

Labeler - Shopko Stores Operating Co., LLC. (023252638)**Registrant** - Shopko Stores Operating Co., LLC. (023252638)**Establishment**

Name	Address	ID/FEI	Business Operations
PREMIER CARE INDUSTRIES, INC		858442403	manufacture(370 12-211)