COOL COMFORT- organic witch hazel swab
Naticura Inc

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.

Naticura Cool Comfort

Active Ingredient

Organic Witch hazel 60%

Purpose

Astringent

Uses

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

Warnings

For external use only.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.(1-800-222-1222)

When using this product

- Do not use more than directed unless told to do so by a doctor
- do not put directly into rectum by using fingers or any mechanical device or applicator
- Store at room temperature 59-86 ^{o}F (15-30 ^{0}C)

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
- Dispose of pad in trash after use.Do not flush
- children under 12 years of age: consult a doctor

Inactive Ingredients

Organic Aloe Vera gel, Organic Glycerin, Natural Grain Alcohol, Organic Jojoba, Organic essential oils of Lavender, Cypress, Geranium.

Principal Display Panel

NDC 71453-211-00

Naticura

CoolComfort

Personal Medicated Cleanisng Pads

Cools, Soothes, Comforts

Hemorrhoidal Pads with Organic Witch Hazel and Aloe

Organic non-GMO Ingredients for your safety: Paraben Free and Chemical Free

100 Moist Soft Cloth Pads

COOL COMFORT

organic witch hazel swab

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71453-211
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 101I4J0U34) (WITCH HAZEL - UNII:101I4J0U34)	WITCH HAZEL	60 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
JOJOBA OIL (UNII: 724GKU717M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71453-211-00	100 in 1 PACKAGE	11/29/2017	
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	11/29/2017	

Labeler - Naticura Inc (203502570)

Registrant - Naticura Inc (203502570)

Establishment

Name	Address	ID/FEI	Business Operations
PREMIER CARE INDUSTRIES, INC		858442403	manufacture(71453-211)

Revised: 11/2022 Naticura Inc