FRIDA MOM HEALING FOAM- salicylic acid aerosol, foam Prime Enterprises, 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.

Frida mom Perineal Healing Foam

Active ingredients

Witch Hazel 50%

Purpose

Astringent

Uses

• Helps relieve the local itching and discomfort in the perianal area.

Warnings

For external use only

When using this product

- Avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- 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

- 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

Adults: When practical, cleanse 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 application of this product. Add foam on top of pad or pad liner. Children under 12 years of age: consult a doctor. Apply to the affected area up to 6 times daily or after each bowel movement.

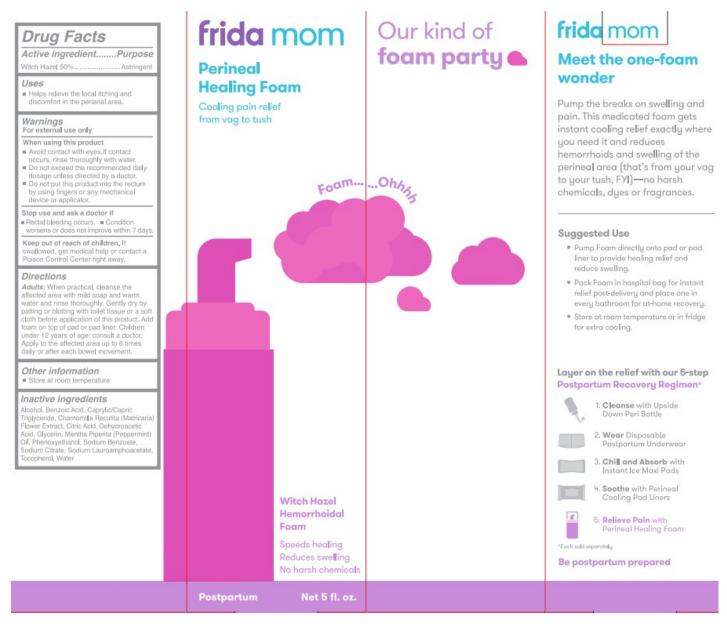
Other information

Store at room temperature

Inactive ingredients

Hamamelis Virginiana (Witch Hazel) Extract, Water, Glycerin, Alcohol, Sodium Lauroamphoacetate, Phenoxyethanol, Benzoic Acid, Tocopherol, Sodium Benzoate, Dehydroacetic Acid, Caprylic/Capric Triglyceride, Sodium Citrate, Mentha Piperita (Peppermint) Oil, Chamomilla Recutita (Matricaria) Flower Extract, Citric Acid

Frida mom Perineal Healing Foam



FRIDA MOM HEALING FOAM salicylic acid aerosol, foam Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:58443-0550

TOPICAL

Active	Ingredient/Active	Moiety
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1	, , , , , , , , , , , , ,		
	Ingredient Name	Basis of Strength	Strength
	WITCH HAZEL (UNII: 10114J0U34) (WTCH HAZEL - UNII:10114J0U34)	WTCH HAZEL	510 mg in 1 mL

Inactive Ingredients			
Ingredient Name Stre			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
PEPPERMINT OIL (UNII: AV092KU4JH)			
CHAMOMILE (UNII: FGL3685T2X)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)			
GLYCERIN (UNII: PDC6A3C0OX)			
ALCOHOL (UNII: 3K9958V90M)			
DEHYDROACETIC ACID (UNII: 2KAG279R6R)			
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
BENZOIC ACID (UNII: 85KN0B0MIM)			
TOCOPHEROL (UNII: R0ZB2556P8)			

Product Characteristics		
Color	yellow (Very Light Yellow)	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:58443- 0550-4	139 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/21/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	04/21/2022	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(58443-0550) , pack(58443-0550) , analysis(58443-0550) , label(58443-0550)

Revised: 4/2022 Prime Enterprises, Inc.