

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

<p>Drug Facts Active ingredient.....Purpose Witch Hazel 50%..... Astringent</p> <p>Uses ■ Helps relieve the local itching and discomfort in the perianal area.</p> <p>Warnings For external use only</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ 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. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ Rectal bleeding occurs. ■ Condition worsens or does not improve within 7 days. <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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.</p> <p>Other information</p> <ul style="list-style-type: none"> ■ Store at room temperature <p>Inactive ingredients Alcohol, Benzoic Acid, Caprylic/Capric Triglyceride, Chamomilla Recutita (Matricaria) Flower Extract, Citric Acid, Dehydroacetic Acid, Glycerin, Mentha Piperita (Peppermint) Oil, Phenoxyethanol, Sodium Benzoate, Sodium Citrate, Sodium Lauroamphoacetate, Tocopherol, Water</p>	<p>frida mom</p> <p>Perineal Healing Foam</p> <p>Cooling pain relief from vag to tush</p> <p>Witch Hazel Hemorrhoidal Foam</p> <p>Speeds healing Reduces swelling No harsh chemicals</p> <p>Postpartum Net 5 fl. oz.</p>	<p>Our kind of foam party 🍷</p> <p>Foam... Ohhhh</p>	<p>frida mom</p> <p>Meet the one-foam wonder</p> <p>Pump the breaks on swelling and pain. This medicated foam gets instant cooling relief exactly where you need it and reduces hemorrhoids and swelling of the perineal area (that's from your vag to your tush, FYI)—no harsh chemicals, dyes or fragrances.</p> <p>Suggested Use</p> <ul style="list-style-type: none"> • Pump Foam directly onto pad or pad liner to provide healing relief and reduce swelling. • Pack Foam in hospital bag for instant relief post-delivery and place one in every bathroom for at-home recovery. • Store at room temperature or in fridge for extra cooling. <p>Layer on the relief with our 5-step Postpartum Recovery Regimen*</p> <ol style="list-style-type: none"> 1. Cleanse with Upside Down Peri Bottle 2. Wear Disposable Postpartum Underwear 3. Chill and Absorb with Instant Ice Maxi Pads 4. Soothe with Perineal Cooling Pad Liners 5. Relieve Pain with Perineal Healing Foam <p>*Each sold separately</p> <p>Be postpartum prepared</p>
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FRIDA MOM HEALING FOAM

salicylic acid aerosol, foam

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58443-0550

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 101I4J0U34) (WTCH HAZEL - UNII:101I4J0U34)	WTCH HAZEL	510 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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: 8SKN0B0MIM)	
TOCOPHEROL (UNII: ROZB2556P8)	

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.