

ALL PURPOSE HEALING BABY CREAM- colloidal oatmeal cream

Spa de Soleil

Skin Relief Cream

Active Ingredient

Oatmeal 1%

Purpose

Skin Protectant

Warnings

For external use only.

When using this product • Avoid contact with eyes. • If contact occurs, rinse thoroughly with water.

Stop using this product and ask a doctor if • condition worsens, or if symptoms last more than 7 days, or if they clear up and occur again within a few days.

Keep out of reach of children. • In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

Directions: For mild to moderate eczema on body, apply as needed or as directed by a physician.

Uses:

Uses • Temporarily protects and helps relieve minor skin itching and irritation due to eczema.

Inactive Ingredients:

Inactive ingredients: Aqua, Isopropyl Palmitate, Glycerin, Ricinus Communis (Castor) Seed Oil, Cetyl Alcohol, Polysorbate 20, Helianthus Annuus (Sunflower) Seed Oil, Distearyltrimonium Chloride, Avena Sativa (Oat) Kernel Oil, Hydroxyethylcellulose, Panthenol, Hydrogenated Castor Oil, Beeswax, Dimethicone, Copernicia Cerifera (Carnauba) Wax, Sodium Hydroxide, *CO Helianthus Annuus (Sunflower Oil), Tocopheryl Acetate (Vitamin E), Prunus Armeniaca (Apricot) Kernel Oil, *CO Calendula Officinalis Flower Extract, *CO Chamomilla Recutita (Matricaria) Flower Extract, Gluconolactone, Sodium Benzoate.

*CO Certified Organic

Warning

Keep out of reach of children.

<p>ALL-PURPOSE HEALING BABY CREAM</p>  <p>by 8 sheep organics 4oz 118ml</p>	<p>Drug Facts</p> <p>Active ingredient Avena Sativa (Oat) Meal Flour 7%</p> <p>Purpose Skin protectant</p> <p>Uses • Temporarily protects and helps relieve minor skin itching and irritation due to eczema.</p> <p>Warnings • For external use only.</p> <p>When using this product • Avoid contact with eyes. • If contact occurs, rinse thoroughly with water. Stop using this product and ask a doctor if • condition worsens, or if symptoms last more than 7 days, or if they clear up and occur again within a few days.</p>	<p>Drug Facts (continues):</p> <p>Keep out of reach of children. • In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.</p> <p>Directions: For mild to moderate eczema only, apply as needed or as directed by a physician.</p> <p>Other information • store at room temperature.</p> <p>Inactive ingredients: Aqua, Isopropyl Palmitate, Glycerin, Ricinus Communis (Castor) Seed Oil, Cetyl Alcohol, Polysorbate 20, Helianthus Annuus (Sunflower) Seed Oil, Dihydroxydimonium Chloride, Avena Sativa (Oat) Kernel Oil, Hydroxyethylcellulose, Panthenol, Hydrogenated Castor Oil, Beeswax, Dimethicone, Copernicia Cerifera (Carnauba) Wax, Sodium Hydroxide, *CO Helianthus Annuus (Sunflower) Oil, Tocopheryl Acetate (Vitamin E), Prunus Armeniaca (Apricot) Kernel Oil, *CO Calendula Officinalis Flower Extract, *CO Chamomilla Recutita (Matricaria) Flower Extract, Gluconolactone, Sodium Benzoate. *CO Certified Organic</p> <p>Made in USA</p>	<p>Manufactured For: 8 Sheep Organics 20155 County Road 2, Elberton, GA 30528 1-800-871-8638</p>
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ALL PURPOSE HEALING BABY CREAM

colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-3301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1.18 mg in 118 mL

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
COPERNICIA CERIFERA (CARNAUBA) WAX (UNII: R12CBM0EIZ)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
GLYCERIN (UNII: PDC6A3C0OX)	
BEEWAX (UNII: 2Z A36H0S2V)	
PRUNUS ARMENIACA (APRICOT) KERNEL EXTRACT (UNII: 75356789IW)	
MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER)	
RICINUS COMMUNIS (CASTOR) SEED OIL (UNII: D5340Y2I9G)	
HYDROXYETHYLCELLULOSE (UNII: T4V6TWG28D)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL (UNII: 3W1JG795YI)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573Z X3X)	
PANTHENOL (UNII: WW9CM0O67Z)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ)	
AVENA SATIVA (OAT) KERNEL OIL (UNII: 3UVP41R77R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-3301-1	118 mL in 1 CANISTER; Type 0: Not a Combination Product	07/13/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	06/13/2025	

Labeler - Spa de Soleil (874682867)

Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-3301)

Revised: 1/2026

Spa de Soleil