

SUDOCREM SKIN PROTECTANT- zinc oxide cream
LEDA INNOVATIONS USA, INC.

SUDOCREM SKIN PROTECTANT CREAM

Drug Facts

Active ingredient

Zinc oxide (15.29%)

Purpose

Skin protectant

Uses

- Helps treat and prevent Diaper Rash and Incontinence Dermatitis
- Protects chafed skin and minor skin irritations due to diaper rash and helps protect from wetness

Warnings

For external use only.

When using this product

- do not get into eyes

Stop use and ask a doctor if

- conditions worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Apply as needed
- For diaper rash, change wet and soiled diapers promptly, cleanse the diaper area, and allow it to dry. Apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Other information

- Store at room temperature between 15C and 30C (59F to 86F)

- Do not use if safety seal is broken or missing

Inactive ingredients

beeswax, benzyl alcohol, benzyl benzoate, benzyl cinnamate, BHA, cetyl esters, cetyl alcohol, citric acid, lanolin, lavender oil, linalyl acetate, liquid paraffin, microcrystalline wax, paraffin wax, propylene glycol, sodium benzoate, sorbitan sesquioleate, stearic acid, water

Product Packaging

<p>Drug Facts</p> <p>Active ingredient.....Purpose Zinc oxide (15.29%).....Skin protectant</p> <p>Uses <ul style="list-style-type: none"> Helps treat and prevent Diaper Rash and Incontinence Dermatitis Protects chafed skin and minor skin irritations due to diaper rash and helps protect from wetness </p> <p>Warnings For external use only.</p> <p>When using this product <ul style="list-style-type: none"> do not get into eyes Stop use and ask a doctor if conditions worsen symptoms last more than 7 days or clear up and occur again within a few days </p> <p>LOT EXP</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Centre right away.</p> <p>Directions <ul style="list-style-type: none"> Apply as needed For diaper rash, change wet and soiled diapers promptly, cleanse the diaper area, and allow it to dry. Apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged. </p> <p>Other information <ul style="list-style-type: none"> Store at room temperature between 15°C and 30°C (59°F to 86°F) </p> <p>Inactive ingredients: beeswax, benzyl alcohol, benzyl benzoate, benzyl cinnamate, BHA, cetyl esters, cetyl alcohol, citric acid, lanolin, lavender oil, linalyl acetate, liquid paraffin, microcrystalline wax, paraffin wax, propylene glycol, sodium benzoate, sorbitan sesquioleate, stearic acid, water</p>	 <p>Sudocrem[®] Skin Protectant Cream</p> <p>SOOTHES, TREATS AND PROTECTS</p> <p>For the protection, relief and treatment of Diaper Rash, minor skin irritations and Incontinence Dermatitis</p> <p>Zinc Oxide 15.29% Net Wt: 14oz (400g)</p>	 <p>6 24721 51055 8</p> <p>Imported by: LEDA Leda Innovations USA Inc. Brookline MA 02445 USA</p> <p>1-877-957-2229 www.sudocrem.com 196873_s1 Made in Bulgaria</p>
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SUDOCREM SKIN PROTECTANT

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84589-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	152.9 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
LANOLIN (UNII: 7EV65EAW6H)	
LINALYL ACETATE (UNII: 5K47SSQ51G)	
BENZYL CINNAMATE (UNII: V67O3RO97U)	
BENZYL BENZOATE (UNII: N863NB338G)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

BENZYL ALCOHOL (UNII: LKG8494WBH)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84589-002-10	1 in 1 BLISTER PACK	08/06/2024	
1		10 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:84589-002-60	60 g in 1 JAR; Type 0: Not a Combination Product	08/06/2024	
3	NDC:84589-002-12	125 g in 1 JAR; Type 0: Not a Combination Product	08/06/2024	
4	NDC:84589-002-25	250 g in 1 JAR; Type 0: Not a Combination Product	08/06/2024	
5	NDC:84589-002-40	400 g in 1 JAR; Type 0: Not a Combination Product	08/06/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	08/06/2024	

Labeler - LEDA INNOVATIONS USA, INC. (779937036)

Revised: 8/2024

LEDA INNOVATIONS USA, INC.