

DERMATITIS FACE BALM- colloidal oatmeal ointment
Skinfix, 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.

SKINFIX - DERMATITIS FACE BALM (61328-121)

Active Ingredients

Colloidal Oatmeal 5%

Purpose

Skin protectant

Uses

Temporarily protects and helps relieve minor skin irritations and itching due to eczema, rash and dermatitis.

Warnings

For external use only.

Stop use and ask a doctor if

- condition 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 to affected areas as needed.

OTHER INFORMATION

STORE AT 65-75°F. MAY STAIN FABRICS. FOR ADULTS AND CHILDREN TWO YEARS OF AGE AND OLDER.

Inactive Ingredients

Petrolatum, Glycine Soja (Soybean) Oil, Butyrospermum Parkii (Shea) Butter, Simmondsia Chinensis (Jojoba) Seed Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Beeswax, Paraffin, Allantoin, Tocopherol.



DERMATITIS FACE BALM

colloidal oatmeal ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61328-121
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SHEA BUTTER (UNII: K49155WL9Y)	
SOYBEAN OIL (UNII: 241ATL177A)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
ALMOND OIL (UNII: 66YXD4DKO9)	
JOJOBA OIL (UNII: 724GKU717M)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61328-121-12	13.5 g in 1 TUBE; Type 0: Not a Combination Product	02/03/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/03/2022	

Labeler - Skinfix, Inc. (203158183)

Registrant - Skinfix, Inc. (203158183)

Establishment

Name	Address	ID/FEI	Business Operations
Canadian Custom Packaging Company		207062514	manufacture(61328-121)

