

TARGETED BODY BALM- 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 - ECZEMA+ TARGETED BODY BALM (61328-122)

Active Ingredients

Colloidal Oatmeal 2%

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.

When using this product

- Avoid contact with eyes

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 as needed.

Other Information

Store at 65-80°F. May stain fabrics. For adults and children two years of age and older.

Inactive Ingredients

Allantoin, Beeswax, Butyrospermum Parkii (Shea) Butter, Glycine Soja (Soybean) Oil,

Paraffin Wax, Petrolatum, Prunus Amygdalus (Sweet Almond) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol, Zinc Oxide.

15 g



60g



TARGETED BODY BALM

oatmeal ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61328-122
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	2 g in 100 g
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Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SHEANUT OIL (UNII: O88E196QRF)	
SOYBEAN OIL (UNII: 241ATL177A)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
ALMOND OIL (UNII: 66YXD4DKO9)	
JOJOBA OIL (UNII: 724GKU717M)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61328-122-11	60 g in 1 TUBE; Type 0: Not a Combination Product	12/26/2018	
2	NDC:61328-122-05	15 g in 1 PACKAGE; Type 0: Not a Combination Product	06/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/23/2015	

Labeler - Skinfix, Inc. (203158183)

Registrant - Skinfix, Inc. (203158183)

Establishment

Name	Address	ID/FEI	Business Operations
Canadian Custom Packaging Company		207062514	manufacture(61328-122)

Revised: 12/2022

Skinfix, Inc.