

DERMA BREEZE SKIN PROTECTANT CREAM- colloidal oatmeal cream
Greys on International, 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.

Derma Breeze 1% colloidal oatmeal with Trilexon

Drug Facts

Active ingredient

Colloidal oatmeal 1%

Purpose

Skin protectant

Uses

temporarily protects and helps relieve minor skin irritation and itching due to:

- rashes
- eczema

Warnings

For external use only

When using this product

- do not get into 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 immediately

Directions

- apply as needed

Inactive ingredients

Water, Medium-Chain Triglycerides, Distearyltrimonium Chloride, Saccharide Isomerate, Cetostearyl alcohol, Isocetyl Stearate, Curdlan, Lactic Acid, Glyceryl Monostearate, PPG-51/SMDI Copolymer, Phenoxyethanol, Cetyl Alcohol, Propylene Glycol Stearate, Sodium Chloride, Alpha-Tocopherol Acetate, PEG-10 Soy Sterol

Questions or comments?

1-828-507-7177

PRINCIPAL DISPLAY PANEL

Derma Breeze

1% colloidal oatmeal

WITH TRILEXON

SKIN PROTECTANT

CREAM

Relieves symptoms of dry skin

Gentle Daily Use Formula

Steroid Free

Fragrance Free

Oil Free Substance

NDC 69475-5411-0



Derma Breeze

1% colloidal oatmeal

WITH TRILEXON

SKIN PROTECTANT

**SKIN PROTECTANT
CREAM**

Relieves symptoms of dry skin

Gentle Daily Use Formula
Steroid Free
Fragrance Free
Oil Free Substance

Net Wt. 1 oz. (28.35g)

NDC 69475-5411-1



Derma Breeze

1% colloidal oatmeal

WITH TRILEXON



SKIN PROTECTANT CREAM

Relieves symptoms of dry skin

Gentle Daily Use Formula
Steroid Free
Fragrance Free
Oil Free Substance

Net Wt. 35.27 oz. (1 kg)

Relieves symptoms of dry skin:

Itch • Dryness • Scaling/Peeling • Roughness • Redness/Irritation

Drug Facts

Active Ingredient

Colloidal oatmeal 1%

Purpose

Skin protectant

Uses

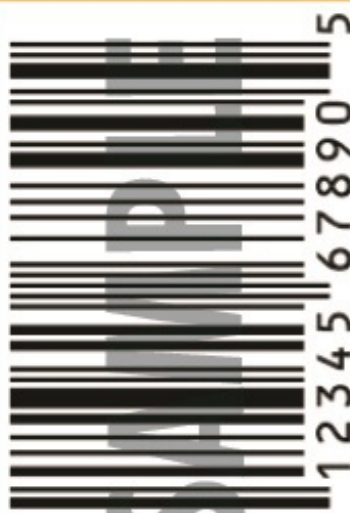
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1-828-507-7177

**Distributed by
King Karat**2460 Old Moultrie Rd, Suite 2
St. Augustine, FL 32086

DERMA BREEZE SKIN PROTECTANT CREAM

colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69475-5411
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CURDLAN (UNII: 6930DL209R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
LACTIC ACID (UNII: 33X04XA5AT)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PPG-51/SMDI COPOLYMER (UNII: KQ9JG3O3YA)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL STEARATE (UNII: MZM1I680W0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-10 SOY STEROL (UNII: FG54K98L0Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69475-5411-0	28.35 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69475-5411-1	1000 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/15/2015	

Labeler - Greyson International, Inc. (848379215)

Revised: 11/2015

Greyson International, Inc.