

TCX SKINCARE- colloidal oatmeal cream
Theraceutix, LLC

tcx skincare® Unique Hydromimetics™

Active Ingredient

Colloidal Oatmeal 2%

Purpose

Skin protectant

Uses

- Temporarily protects and helps relieve minor skin irritation and itching due to dry skin and eczema

Warnings

- **For external use only**

Keep out of reach of children.

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

When using this product:

- Do not get into eyes
- Stop use and ask doctor if condition worsens

Directions

- Apply to affected areas of skin twice daily

Inactive Ingredients

Caprylic/Capric Triglyceride, Carbomer, Cetyl Alcohol, Cetyl Palmitate, Dimethicone, DMDM Hydantoin, Glycerin, Glyceryl Stearate, Iodopropynyl Butylcarbamate, Mineral Oil, Octyldodecanol, PEG-40 Stearate, Phenoxy Ethanol, Sodium Hydroxide, Water

Package/Label Principal Display Panel - Carton Label

ECZEMA AND DRY SKIN RELIEF

Skin Protectant

tcx skincare®
UNIQUE HYDROMIMETICS™

2 fl oz/59 mL



Carton Label

Package/Label Principal Display Panel - Sample Label

tcx skincare®
UNIQUE HYDROMIMETICS™

0.3 oz

Eczema and Dry Skin Relief
Skin Protectant

Directions: Apply to affected areas of skin twice daily

SAMPLE NOT FOR RESALE

tcxskincare.com

Drug Facts**Active IngredientPurpose**
Colloidal Oatmeal 2% Skin protectant

PEEL HERE FOR MORE DRUG FACTS

Eczema and Dry Skin Relief
Skin ProtectantDirections: Apply to affected
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SAMPLE NOT FOR RESALE

tcxskincare.com

Sample Label

TCX SKINCARE

colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49449-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
MINERAL OIL (UNII: T5L8T28FGP)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
OCTYLDODECANOL (UNII: 461N1O614Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49449-100-01	59 g in 1 JAR; Type 0: Not a Combination Product	05/17/2012	
2	NDC:49449-100-02	9 g in 1 JAR; Type 0: Not a Combination Product	05/17/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	05/17/2012	

Labeler - Theraceutix, LLC (078353793)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing, Inc.		793406000	MANUFACTURE(49449-100)

Revised: 12/2023

Theraceutix, LLC