

THERAPLEX ECZEMA THERAPY MOISTURIZING SKIN PROTECTANT- colloidal oatmeal lotion

The Theraplex Company, LLC

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.

Theraplex

Drug Facts

Active Ingredients

Colloidal Oatmeal 1%

Purpose

Skin Protectant

Uses

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

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 right away.

Directions

apply as needed, or as directed by your doctor.

Other information

• store at room temperature • keep from freezing

Inactive Ingredients

cyclomethicone, microcrystalline wax, petrolatum (special fraction)

Questions?


call **1-888-437-2753**

Does not contain antibiotics.

Not tested on animals.

Distributed by:
 The Theraplex Company, LLC
 Memphis, TN 38119
 Steroid Free
 Fragrance Free
 Paraben Free
 Preservative Free
 Gluten Free
 Noncomedogenic
 Hypoallergenic

Packaging

 <p>theraplex ECZEMA THERAPY</p> <p>Moisturizing Skin Protectant with Colloidal Oatmeal Temporarily protects and helps relieve minor skin irritations and itching due to ■ eczema ■ rashes</p> <p>Net Wt. 6oz. (170.1g)</p>	<p>Drug Facts</p> <p>Active Ingredient Colloidal Oatmeal 1%..... Skin Protectant</p> <p>Uses temporarily protects and helps relieve minor skin irritation and itching due to: ■ eczema ■ rashes</p> <p>Warnings For external use only When using this product do not get into eyes.</p>	<p>Stop and ask a doctor if ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions apply as needed, or as directed by your doctor.</p> <p>Other information ■ store at room temperature ■ keep from freezing</p> <p>Inactive Ingredients cyclomethicone, microcrystalline wax, petrolatum (special fraction)</p> <p>Questions? call 1-888-437-2753</p>	<p>Does not contain antibiotics. Not tested on animals.</p> <p>Distributed by: The Theraplex Company, LLC Memphis, TN 38119</p> <p>Please visit us at: www.theraplex.com for the complete line of Theraplex skin care products.</p>
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DRUG FACTS

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Steroid Free
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theraplex
ECZEMA THERAPY

Moisturizing Skin Protectant
 with Colloidal Oatmeal

THERAPLEX ECZEMA THERAPY MOISTURIZING SKIN PROTECTANT			
colloidal oatmeal lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62917-350
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)		OATMEAL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62917-350-01	128 g in 1 TUBE; Type 0: Not a Combination Product	11/01/2013	07/01/2020
2	NDC:62917-350-06	170.1 g in 1 JAR; Type 0: Not a Combination Product	01/23/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	11/01/2013	

Labeler - The Theraplex Company, LLC (363529392)

Establishment

Name	Address	ID/FEI	Business Operations
Memphis Contract Packaging, Inc.		185390010	manufacture(62917-350)

Revised: 2/2018

The Theraplex Company, LLC