

## **THERAPLEX HEALING EMOLLIENT- petrolatum cream**

**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.*

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### **theraplex HEALING EMOLLIENT**

#### ***Drug Facts***

#### ***Active Ingredient***

Petrolatum (65%)

#### ***Purpose***

Skin Protectant

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### ***Uses***

• temporarily protects and helps relieve chapped or cracked skin and lips • helps protect from the drying effects of wind and cold weather • temporarily protects minor: • cuts • scrapes • burns

#### ***Warnings For external use only***

***When using this product*** do not get into eyes.

***Stop and ask a doctor if*** • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days

***Do not use on*** • deep or puncture wounds • animal bites • serious burns

***Directions*** apply as needed, or as directed by your doctor.

***Inactive Ingredients*** cyclomethicone, microcrystalline wax

***Other information*** • store at room temperature • keep from freezing

***Questions?*** call **1-888-437-2753**

Clinically-proven **Theraplex Healing Emollient** combines a unique enriched special petrolatum fraction (ESPF) with a novel hydrosilicone delivery system that deeply penetrates severely dry skin. Dermatologists have recommended this healing formulation for years because of its ability to deliver soothing moisturization and long-lasting skin barrier protection with no irritation to sensitive, compromised skin.

- **Noncomedogenic (Won't Clog Pores)**
- **Hypoallergenic**
- **Preservative-Free**
- **Fragrance-Free**
- **Paraben-Free**
- **Gluten-Free**

Skin Protectant • For Severely Dry & Sensitive Skin

**Dermatologist recommended for adults & children**

Net Wt. 8oz. (226.7g)

Distributed by:

The Theraplex Company, LLC

Memphis, TN 38119

[www.theraplex.com](http://www.theraplex.com)

**Packaging**

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**HEALING EMOLLIENT**  
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 Dermatologist recommended for adults & children  
 Net Wt. 8oz. (226.7g)

Jar Screen



Bottom Label



Top Label

THERAPLEX HEALING EMOLLIENT			
petrolatum cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62917-065
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	65 g in 100 g
Inactive Ingredients			
	Ingredient Name	Strength	
	CYCLOMETHICONE (UNII: NMQ347994Z)		

MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62917-065-08	226.7 g in 1 JAR; Type 0: Not a Combination Product	10/23/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/23/2015	

**Labeler** - The Theraplex Company, LLC (363529392)

### Establishment

Name	Address	ID/FEI	Business Operations
Memphis Contract Packaging, Inc.		185390010	manufacture(62917-065)

Revised: 10/2015

The Theraplex Company, LLC