

## **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

#### ***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

***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

***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

Distributed by:  
The Theraplex Company, LLC  
Memphis, TN 38119  
[www.theraplex.com](http://www.theraplex.com)

## Packaging

<b>Drug Facts</b>		<b>theraplex</b> <b>HEALING EMOLLIENT</b> Skin Protectant • For Severely Dry & Sensitive Skin Dermatologist recommended for adults & children Net Wt. 8oz. (226.7g)
<b>Active Ingredient</b> Petrolatum (65%)	<b>Purpose</b> Skin Protectant	
<b>Uses</b> 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	<b>Directions</b> apply as needed, or as directed by your doctor.	
<b>Warnings</b> For external use only When using this product do not get into eyes.	<b>Other information</b> ■ store at room temperature ■ keep from freezing	
	<b>Inactive Ingredients</b> cyclomethicone, microcrystalline wax	
	<b>Questions?</b> call 1-888-437-2753	

## Drug Facts Label

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Bottom Label



Top Label

## THERAPLEX HEALING EMOLLIENT

petrolatum cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62917-065
<b>Route of Administration</b>	CUTANEOUS		

### 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:62917-065-02	56.6 g in 1 JAR; Type 0: Not a Combination Product	05/01/2017	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/01/2017	

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

Revised: 2/2017

The Theraplex Company, LLC