

**PETROCORT ANTIPRURITIC LIP 21- hydrocortisone lipstick**  
**Clinical Formula LLC**

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**Petrocort Antipruritic Lip Balm #21**

**Drug Facts**

**Active Ingredient (in percentage)**

Hydrocortisone 0.5%

**Purpose**

For relief of minor skin irritation.

**USES:**

Adults and children 5 years and over: For the temporary relief of minor skin irritations and rashes. Help prevent and temporarily protect chafed, chapped, cracked, windburned or sunburned lips.

**WARNINGS:**

For external use only. If condition worsens, does not improve, or symptoms persist for more than 7 days or clear up and reoccur again within a few days, discontinue use and consult a physician. Keep from heat.

**Keep out of reach of children.**

**DIRECTIONS:**

Apply to lips 1-3 times daily or use as directed by physician. For use on children under 5 years of age, consult a physician.

**INACTIVE INGREDIENTS:**

Petrolatum, Syncrowax HGL-C, Syncorwax ERL-C, Padimate-O Mineral Oil, Propylparaben, Fragrance, FD & C Yellow # 5, FD & C Blue # 1.

**Package Labeling:**

# Clinical Formula™

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Net Wt. 0.15 OZ.

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Clinical Formula, LLC  
Newport Beach, CA 92663

# PETROCORT ANTIPRURITIC LIP 21

hydrocortisone lipstick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51822-021
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	0.005 g in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>C18-36 ACID TRIGLYCERIDE</b> (UNII: ZRA72DR3R7)	
<b>PADIMATE O</b> (UNII: Z11006CMUZ)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51822-021-15	4.25 g in 1 TUBE; Type 0: Not a Combination Product	12/26/2017	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M017	12/26/2017	

**Labeler** - Clinical Formula LLC (084120658)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Clinical Formula LLC		084120658	manufacture(51822-021)