

**LIPCOTZ LIP BALM/SUNSCREEN - titanium dioxide, zinc oxide lipstick  
Fallien Cosmeceuticals, LTD.**

*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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**LIPCÔTZ**

**Drug Facts**

**Active Ingredients**

Titanium Dioxide 4.0%

Zinc Oxide 5.5%

**Purpose**

Sunscreen

Sunscreen

**Uses:**

Helps prevent sunburn; higher SPF gives more sunburn protection for skin that sunburns easily

**Warnings:**

For External Use Only. Stop use and consult a physician if rash or irritation develops. Avoid contact with eyes.

**Keep out of reach of children:**

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

**Directions:**

Apply generously to lips prior to sun exposure. Reapply often and after water activity, excessive perspiration or towel drying. Children under 6 years old, consult a physician.

**Inactive Ingredients:**

Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbic Acid, Ascorbyl Palmitate, C12-15 Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Dipropylene Glycol Dicaprylate-Caprate, Ethylhexyl Palmitate, Flavor, Helianthus Annus (Sunflower) Seed Wax, Hexyldecanol, Hexyldecyl Laurate, Iron Oxides, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxy Stearic Acid, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Offinale (Ginger) Root Oil

**Principal Display Panel – Carton Label**

NDC 58892-125-87

**SPF 45**

**LIPCÖTZ**

Contains Only Titanium & Zinc™

**SPF 45**

**Contains Only Titanium & Zinc™**

**Ultra High Sun Protection no chemical sunscreen filters**

Net Wt. .14 Oz./ 4.5 g

For Information Call:

800-332-5536

Manufactured for: Fallene, Ltd

West Norriton, PA

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**Drug Facts**

# LIPCOTZ LIP BALM/SUNSCREEN

titanium dioxide, zinc oxide lipstick

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-125
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	40 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	55 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
Aluminum Oxide (UNII: LMI26O6933)	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
Aluminum Stearate (UNII: U6XF9NP8HM)	
Ascorbic Acid (UNII: PQ6CK8PD0R)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	
C12-15 Alkyl Benzoate (UNII: A9EJ3J61HQ)	
Ceresin (UNII: Q1LS2UJO3A)	
Cetearyl Isononanoate (UNII: P5O01U99NI)	
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Propylene Glycol Dicaprylate/Dicaprate (UNII: O4446S9CRA)	
Ethylhexyl Palmitate (UNII: 2865993309)	
Kiwi Fruit (UNII: 71ES77LGJC)	
Lime (Citrus) (UNII: 8CZS546954)	
Sunflower Oil (UNII: 3W1JG795YI)	
Hexyldecanol (UNII: 151Z7P1317)	
Hexyldecyl Laurate (UNII: 0V595C1P6M)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Lecithin, Soybean (UNII: 1D56QDM62)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Alpha-Tocopherol (UNII: H4N855PNZ1)	
.ALPHA.-Tocopherol Acetate, D- (UNII: A7E6112E4N)	
Ginger Oil (UNII: SAS9Z1SVUK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-125-87	1 in 1 CARTON		
1		4.5 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/01/2005	

**Labeler** - Fallien Cosmeceuticals, LTD. (958388357)

## Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE, PACK

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS

Revised: 9/2010

Fallien Cosmeceuticals, LTD.