

SOLAR PROTECTION FORMULA LIPTECT 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.

DRUG FACTS

Active Ingredients:

Titanium Dioxide 4.0%

Zinc Oxide 5.5%

Purpose

Sunscreen

Sunscreen

Uses:

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings:

- *For external use only.*

Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs.

When using this product, keep out of eyes. Rinse with water to remove.

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

Directions:

- Apply liberally 15 minutes before sun exposure.
- Reapply:
 - After 80 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
- Children under 6 months: Ask a doctor
- **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10:00 a.m.-2 p.m.
 - Wear long-sleeved shirts, pants, hats, and sunglasses

Other Information:

- Protect this product from excessive heat and direct sun

- May stain some fabrics

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 Annuus (Sunflower) Seed Wax, Hexyldecanol, Hexyldecyl Laurate, Iron Oxides, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Offinale (Ginger) Root Oil

Manufactured exclusively for: Fallien Cosmeceuticals Ltd., West Norriton, PA 19403

Principal Display Panel – 4.5g Carton Label

NDC 58892-240-45

SOLAR

PROTECTION

FORMULA[®]

LIPTECT

SPF 45

Broad Spectrum

UVA/UVB

Water Resistant (80 minutes)

Ultra High Sun Protection

No Chemical Sunscreen Filters

.14 oz. Net Wt. (4.5 g)

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-240
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: SO2LOH54Z) (Zinc Oxide - UNII:SO2LOH54Z)	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:58892-240-45	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	01/02/2004	

Labeler - Fallien Cosmeceuticals, LTD. (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-240)

Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE(58892-240) , PACK(58892-240)

Revised: 12/2012

Fallien Cosmeceuticals, LTD.