

COTZ SPF 35 SUNSCREEN - zinc oxide lotion
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.

CoTZ SPF 35 Sunscreen

DRUG FACTS

Active Ingredients:

Zinc Oxide 20%.

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- Provides protection from UVA & UVB rays that may contribute to premature aging of the skin
- Retains SPF up to 40 minutes of water immersion or perspiring

Warnings

- For external use only
- Avoid contact with eyes. In case of eye contact, flush eyes with water thoroughly
- Do not use if sensitive to ingredients
- Discontinue use if irritation occurs. Consult a doctor or healthcare professional if irritation persists
- For use on children less than 6 months of age, consult a doctor
- Keep this and all medications out of the reach of children
- If swallowed, get medical help or contact a Poison Control Center

Directions

- Apply generously and uniformly to all exposed skin areas before exposure to sunlight
- Continue to rub in until fading occurs, especially in hair bearing areas
- Reapply as needed and after washing, swimming, towel drying, or sweating for maximum protection.

Other Information

- Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.
- May stain some fabrics

Inactive Ingredients:

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Lauryl PEG/PPG 18/18 Methicone, Methicone, PEG-10 Dimethicone, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexadecyl Ascorbate, Tocopheryl Acetate, Triethanolamine,

Triethoxycaprylylsilane,

**Manufactured
exclusively for
Fallene, Ltd.
West Norriton, PA 19403
Made in USA**

Principal Display Panel – 3.5oz Carton Label

NDC 58892-118-01

Dermatologist

**Recommended for
Ultra Sensitive Skin**

CoTZ®

20% Zinc Oxide

vanishing formula

Pure Mineral

Sun protection

Moisturizing

water resistant

uva/uvb

SPF 35

Net. Wt. 3.5 oz./ 100g

DRUG FACTS

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Zinc Oxide 20%..... Sunscreen

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- Excellent for Ultra Sensitive Skin
- Non-irritating
- Use on Face and Body
- No Parabens, Oils or Fragrances
- Specially formulated with no irritating "Chemical Sunscreen Filters"

DRUG FACTS

Inactive Ingredients:

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Lauryl PEG/PPG 18/18 Methicone, Methicone, PEG-10 Dimethicone, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexadecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane,

Manufactured exclusively for Fallene, Ltd. West Norriton, PA 19403 Made in USA

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Dermatologist Recommended for Ultra Sensitive Skin



PURE MINERAL SUN PROTECTION

MOISTURIZING WATER RESISTANT UVA/UVB

SPF 35

Net. Wt. 3.5 oz./ 100g

CōTZ 20% Zinc Oxide SPF 35

- Specially formulated without irritating chemical sunscreen filters
- Uniquely formulated to offer sheer transparent protection on most complexions
- Silky, smooth aesthetic elegance
- Paraben, oil and fragrance free
- Provides superb photostable performance
- Zinc Oxide helps to assure full spectrum UVA/UVB protection.

Everyone requires daily, year round UVA protection

- UVA radiation is consistently the same all day and all year long
- The effects of UVA damage are cumulative
- UVA radiation is responsible for deep skin damage that results in skin aging, such as wrinkling



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COTZ SPF 35 SUNSCREEN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-118
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Edetate Disodium (UNII: 7FLD91C86K)	
Glycerin (UNII: PDC6A3C0OX)	
Hydroxystearic Acid (UNII: 933ANU3H2S)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Sodium Chloride (UNII: 451W47IQ8X)	
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
.Alpha.-Tocopherol Acetate, D- (UNII: A7E6112E4N)	
Trolamine (UNII: 9O3K93S3TK)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-118-01	1 in 1 CARTON		
1		100 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2011	

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

Establishment			
Name	Address	ID/FEI	Business Operations
Harmony Labs Inc		105803274	MANUFACTURE, PACK

Revised: 6/2011

Fallien Cosmeceuticals, LTD.