

INGENUE - zinc oxide cream

Ingenu, 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.

Drug Facts

Active Ingredient:

Zinc Oxide 14.5%

Purpose:

Sunscreen

Keep out of reach of children. If product is swallowed, get medical help or contact a poison control center right away.

Uses:

Helps prevent sunburn

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.

Directions:

Apply liberally 15 minutes before sun exposure

Use a water resistant sunscreen if swimming or sweating

Reapply 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 a.m. - 2 p.m.

wear long-sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients:

Alcohol, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Glycerin, C13-14 Isoparaffin, Cyclomethicone, Glyceryl Stearate, Laureth-7, PEG-100 Stearate, Polyacrylamide, Citrullus Lanatus (Watermelon) Fruit Extract, Steareth-21, Synthetic Beeswax, Dimethicone, Olea Europaea (Olive) Fruit Oil, Helianthus Annuus (Sunflower) Seed Oil, Camellia Sinensis (Green Tea) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Daucus Carota Sativa (Carrot) Extract, Glycyrrhiza Glabra (Licorice) Extract, Lentinus Edodes (Shiitake Mushroom) Extract,

Macrocystis Pyrifera (Kelp) Extract, Pisum Sativum (Pea) Extract, Caprylyl Glycol, Castor Oil Phosphate, Sodium Benzoate, Potassium Sorbate, Annatto, Dipotassium Glycyrrhizinate, Disodium EDTA, Ferulic Acid, Maltodextrin, Phyllanthus Emblica Fruit Extract, Sodium Hyaluronate, Tetrahydro Curcuminoids, Sorbic Acid, Tetrahexyldecyl Ascorbate, Phospholipids, Retinyl Palmitate, Tocopheryl Acetate, Ascorbyl Palmitate, Tocopherol, Sodium Dehydroacetate, Phenoxyethanol, water.



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Other information

- protect this product from excessive heat and direct sun

Vegan / végétalien

Healthy Ingredients / ingrédients sains

Certified by PETA as Cruelty Free / certifié sans cruauté animale par PETA

Recyclable / recyclable

Sustainable / durable

Made in the USA / Fait aux É.-U.

Without / sans:

Parabens / parabènes

Gluten / gluten

Artificial Colors / colorants artificiels

Fragrance / fragrance

Animal Ingredients / ingrédients de source animale

Animal Testing / tests sur les animaux

Sweatshops / ateliers d'exploitation

Triclosan / triclosan

Sulfates / sulfates

Phthalates / phtalates

Manufactured for distribution by /
Fabriqué pour être distribué par
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The new face of Hollywood is healthy, youthful & eco. This A-List beauty treatment blends the best clinically proven youth enhancing actives and the best of nature. Best Performance™ skin care is truly an eco-luxury.

Sheer Shield™ Matte Day Cream Broad Spectrum SPF 20 provides essential, lightweight moisture with a mattifying natural sunscreen to prevent against UVA/UVB damage.

Benefits / bienfaits:

UVA/UVB Protection / protection UVA/UVB

Mattifying / Matifiante

Blends Flawlessly / se combine parfaitement

No White Residue / aucun résidu blanc

Lightweight / léger

Antioxidant Renewal / renouvellement antioxydant

Moisture / hydratation

Vitamin & Nutrient Fortified / enrichi de vitamines et de nutriments

FOR ALL SKIN TYPES / pour tous les types de peau

BEST PERFORMANCE™

**SHEER SHIELD™
MATTE DAY CREAM**

**BROAD SPECTRUM
SPF 20**

**CLINICALLY PROVEN
UVA/UVB PROTECTION
DERMATOLOGIST
TESTED**

ÉPROUVÉE EN CLINIQUE
MIS À L'ESSAI PAR LES
DERMATOLOGUES

1.7 FL OZ | 50 ML E



Printed with Vegetable Inks /
Imprimé avec des encres végétales

Made in the USA / Fait aux É.-U.

INGENUE

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54151-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LAURETH-7 (UNII: Z95S6G8201)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
WATERMELON (UNII: 231473QB6R)	
STEARETH-21 (UNII: 53J3F32P58)	
SYNTHETIC WAX (1800 MW) (UNII: 248P1AUJ90)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMOMILE (UNII: FGL3685T2X)	
CUCUMBER (UNII: YY7C30VXJT)	
CARROT (UNII: L56Z1JK48B)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
LENTINULA EDODES MYCELIUM (UNII: CU2S39TB8O)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
PEA (UNII: W4X7H8GYFM)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CASTOR OIL (UNII: D5340Y2I9G)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ANNATTO (UNII: 6PQP1V1B6O)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FERULIC ACID (UNII: AVM951ZWST)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
PHYLLANTHUS EMBLICA FRUIT (UNII: YLX4CW2576)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TETRAHYDRO DIFERULO YLMETHANE (UNII: 00U0645U03)	
SORBIC ACID (UNII: X045WJ989B)	

TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SOYBEAN (UNII: L7HT8F1ZOD)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54151-10 1-26	1 in 1 BOX		
1		50 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/15/2012	

Labeler - Ingenue, LLC (078662060)

Establishment

Name	Address	ID/FEI	Business Operations
Smith & Vandiver Corp		061973426	manufacture(54151-101)

Revised: 12/2012

Ingenue, LLC