

IM PURE CICA SUNSCREEN- zinc oxide, titanium dioxide lotion
Normalest Co., 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.

180131 SUNTIQUE I'M PURE CICA SUNCREAM_BOX



I'M PURE CICA SUNSCREEN

Drug Facts

Active ingredients	Purpose
Titanium Dioxide (3.1%) Zinc Oxide (11.6%)	} 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
- When using this product** keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor** if rash occurs
- Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- **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. to 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - children under 6 months of age: Ask a doctor
 - reapply at least every 2 hours.
 - use a water resistant sunscreen if swimming or sweating.

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

1,2-hexanediol, aluminum hydroxide, anthemis nobilis flower oil, butylene glycol, caprylyl glycol, cardiospermum halicacabum flower/leaf/vine extract, centella asiatica extract, cetyl ethylhexanoate, cyclomethicone, dicaprylyl carbonate, dimethicone crosspolymer, distardimonium hectorite, echium skarlaginense seed oil, ethylhexylglycerin, flaxseed glycosides, glycyrrhiza lemenii (licorice), helianthus annuus (sunflower) seed oil, helianthus annuus (sunflower) seed oil unsaponifiables, hostyria cordata extract, hydrogen dimethicone, madecassoside, magnesium sulfate, octyldodecanol, pentylene glycol, phenyl trimethicone, polyglyceryl-2 dipolyhydrazostearate, polyglyceryl-3 polydimethylsilyloxyethyl dimethicone, propanediol, pullulan, saccharide hydrolysate, salvia hispanica seed extract, stearic acid, tocopherol, water

Manufactured for Normalest Co., Ltd.
 5F 297-1, Yeonseo-ro, Eunpyeong-gu, Seoul, Korea

MADE IN KOREA WWW.SUNTIQUE.NET

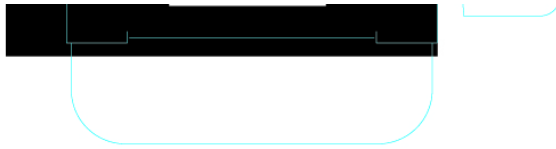


SUNCARE A TO Z

50ml

1.69 FL. OZ.

www.suntique.net



Active Ingredients

Zinc Oxide (11.6%)

Titanium Dioxide (3.1%)

Inactive Ingredients

Water, Cyclomethicone, Hydrogen Dimethicone, Aluminum Hydroxide, Stearic Acid, Dicaprylyl Carbonate, Propanediol, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Dimethicone Crosspolymer, Phenyl Trimethicone, Salvia Hispanica Seed Extract, Centella Asiatica Extract, Houttuynia Cordata Extract, 1,2-Hexanediol, Saccharide Hydrolysate, Fructooligosaccharides, Pullulan, Cetyl Ethylhexanoate, Disteardimonium Hectorite, Magnesium Sulfate, Polyglyceryl-2 Dipolyhydroxystearate, Helianthus Annuus (Sunflower) Seed Oil, Anthemis Nobilis Flower Oil, Ethylhexylglycerin, Octyldodecanol, Echium Plantagineum Seed Oil, Cardiospermum Halicacabum Flower/Leaf/Vine Extract, Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables, Tocopherol, Galactomyces Ferment Filtrate, Butylene Glycol, Pentylene Glycol, Caprylyl Glycol, Madecassoside

IM PURE CICA SUNSCREEN

zinc oxide, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72284-0004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.82 g in 50 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.56 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
SUNFLOWER SEED OIL GLYCERETH-8 ESTERS (UNII: 358X17CAT0)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
CARDIOSPERMUM HALICACABUM WHOLE (UNII: 185RQ97K0V)	
MADECASSOSIDE (UNII: CQ2F5O6YIY)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	

CENTELLA ASIATICA LEAF (UNII: 6810070TYD)
INVERT SUGAR (UNII: ED959S6ACY)
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)
MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
OCTYLDODECANOL (UNII: 461N1O614Y)
ECHIUM PLANTAGINEUM SEED OIL (UNII: PIB7XBU8XW)
WATER (UNII: 059QF0KO0R)
CYCLOMETHICONE (UNII: NMQ347994Z)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
PROPANEDIOL (UNII: 5965N8W85T)
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
SALVIA HISPANICA SEED (UNII: NU0OLX06F8)
HOUTTUYNIA CORDATA WHOLE (UNII: O3E12ZLW5T)
PULLULAN (UNII: 8ZQ0AYU1TT)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
TOCOPHEROL (UNII: R0ZB2556P8)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
FOSEFRUCTOSE (UNII: M7522JYX1H)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72284-0004-1	1 in 1 BOX	03/06/2019	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/06/2019	

Labeler - Normalest Co., Ltd. (694812877)

Registrant - Normalest Co., Ltd. (694812877)

Establishment

Name	Address	ID/FEI	Business Operations
Normalest Co., Ltd.		694812877	manufacture(72284-0004)

Revised: 3/2019

Normalest Co., Ltd.