

SUNSCREEN 100- titanium dioxide cream
CMS LAB Inc.

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.

Sunscreen 100

Active ingredients

Titanium Dioxide (2.52%)

Purpose

Sunscreen

Uses

Helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

For external use only

Do not use when skin is red, inflamed, irritated, or painful

When using this product

- do not apply on other parts of the body
- do not use on damaged or broken skin
- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water
- do not apply directly to wound or open cut

Stop use and ask a doctor if

- Rash or irritation on skin develops and lasts

Directions

- Apply the adequate amount onto the entire face at the last stage of your skin care routine.
Re-apply frequently and generously to maintain protection. the palm of the hands and pat lightly with the fingertips.
- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water-resistant sunscreen if swimming or sweating.
- Children under 6 months of age: ask a doctor

Inactive ingredients

WATER, DIBUTYL ADIPATE, POLYGLYCERYL-2 CAPRATE, SUCROSE STEARATE, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, STEARIC ACID, ALUMINA, GLYCERYL CAPRYLATE, SQUALANE, GLYCERIN, C12-15 ALKYL BENZOATE, PROPANEDIOL, 1,2-HEXANEDIOL, CENTELLA ASIATICA EXTRACT, HOUTTUYNIA CORDATA EXTRACT, PORTULACA OLERACEA EXTRACT, BUTYLOCTYL SALICYLATE, ARACHIDYL ALCOHOL, BEHENYL ALCOHOL, ARACHIDYL GLUCOSIDE, POLYSILICONE-15, DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE, ETHYLHEXYL TRIAZONE, CETEARYL ALCOHOL, SACCHARIDE HYDROLYSATE, SALVIA HISPANICA SEED EXTRACT, CURCUMA LONGA (TURMERIC) ROOT EXTRACT, GLYCERYL STEARATE, ECHIUUM PLANTAGINEUM SEED OIL, CARDIOSPERMUM HALICACABUM FLOWER/LEAF/VINE EXTRACT, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL UNSAPONIFIABLES, TOCOPHEROL, PANTHENOL, SODIUM STEAROYL GLUTAMATE, POLYACRYLATE CROSSPOLYMER-6, t-BUTYL ALCOHOL, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, ROSE FLOWER OIL, JUNIPERUS MEXICANA OIL, XANTHAN GUM, ETHYLHEXYLGLYCERIN, HYDROGENATED LECITHIN, CERAMIDE 3 (CERAMIDE NP), SUCROSE STEARATE, CHOLESTEROL, PALMITIC ACID, CHOLESTERYL MACADAMIATE, SACCHARIDE ISOMERATE, HYDROLYZED LUPINE PROTEIN

Sunscreen 100



| PERFECT SHIELD |

Sunscreen 100

SPF 50+/PA++++

A superior sun protector that perfectly shields skin from UVA/UVB rays



All skin types

DERMATOLOGICALLY TESTED

Sunscreen 100 provides broad and high UVA/UVB protection and is gentle enough to apply on sensitive skin.

DIRECTIONS: Apply onto the entire face at the last stage of your skin care routine. Re-apply frequently and generously to maintain protection.

NOTICE: For external use only. Stop use if irritation occurs. Keep out of reach of children.

INGREDIENTS: WATER, DIBUTYL ADIPATE, GLYCERIN, C12-15 ALKYL BENZOATE, TITANIUM DIOXIDE, DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE, BUTYLOCTYL SALICYLATE, POLYSILICONE-15, ETHYLHEXYL TRIAZONE, 1,2-HEXANEDIOL, BEHENYL ALCOHOL, ARACHIDYL ALCOHOL, CETEARYL ALCOHOL, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, ECHIUM PLANTAGINEUM SEED OIL, ROSE FLOWER OIL, JUNIPERUS MEXICANA OIL, PORTULACA OLERACEA EXTRACT, CENTELLA ASIATICA EXTRACT, HOUSTONIA CORDATA EXTRACT, CURCUMA LONGA (TURMERIC) ROOT EXTRACT, SALVIA HISPANICA SEED EXTRACT, CARDIOSPERMUM HALI CACABUM FLOWER/LEAF/VINE EXTRACT, GLYCERYL STEARATE, CETYL ALCOHOL, ARACHIDYL GLUCOSIDE, OCTYLDODECANOL, SODIUM STEAROYL GLUTAMATE, PROPANEDIOL, POLYGLYCERYL-2 CAPRATE, PANTHENOL, POLYACRYLATE CROSSPOLYMER-6, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDI METHYL TAURATE COPOLYMER, SUCROSE STEARATE, XANTHAN GUM, STEARIC ACID, SACCHARIDE HYDROLYSATE, ALUMINA, ETHYLHEXYL GLYCERIN, GLYCERYL CAPRYLATE, SQUALANE, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, UNSAPONIFIABLES, HYDROGENATED LECITHIN, T-BUTYL ALCOHOL, CERAMIDE NP, CHOLESTEROL, CHOLESTERYL MACADAMATE, PALMITIC ACID, TOCOPHEROL, SACCHARIDE ISOMERATE, HYDROLYZED LUPINE PROTEIN

e 50 ml

Period after opening: 12 months

Made in Korea
www.cellfusionc.co.kr
NEO CMS™

Drug Facts

Active Ingredient	Purpose
Titanium Dioxide (2.52%)	Sunscreen

Uses Helps prevent sunburn

Warnings

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Stop use and ask a doctor if

- Rash or irritation on skin develops and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- Apply the adequate amount onto the entire face at the last stage of your skin care routine. Re-apply frequently and generously to maintain protection, the palm of the hands and pat lightly with the fingertips.
- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water-resistant sunscreen if swimming or sweating.
- Children under 6 months of age, ask a doctor

Other information

- Avoid storing product in direct sunlight.

Inactive Ingredients

WATER, DIBUTYL ADIPATE, POLYGLYCERYL-2 CAPRATE, SUCROSE STEARATE, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, STEARIC ACID, ALUMINA, GLYCERYL CAPRYLATE, SQUALANE, GLYCERIN, C12-15 ALKYL BENZOATE, PROPANEDIOL, 1,2-HEXANEDIOL, CENTELLA ASIATICA EXTRACT, HOUSTONIA CORDATA EXTRACT, PORTULACA OLERACEA EXTRACT, BUTYLOCTYL SALICYLATE, ARACHIDYL ALCOHOL, BEHENYL ALCOHOL, ARACHIDYL GLUCOSIDE, POLYSILICONE-15, DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE, ETHYLHEXYL TRIAZONE, CETEARYL ALCOHOL, SACCHARIDE HYDROLYSATE, SALVIA HISPANICA SEED EXTRACT, CURCUMA LONGA (TURMERIC) ROOT EXTRACT, GLYCERYL STEARATE, ECHIUM PLANTAGINEUM SEED OIL, CARDIOSPERMUM HALI CACABUM FLOWER/LEAF/VINE EXTRACT, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, UNSAPONIFIABLES, TOCOPHEROL, PANTHENOL, SODIUM STEAROYL GLUTAMATE, POLYACRYLATE CROSSPOLYMER-6, 1-BUTYL ALCOHOL, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDI METHYL TAURATE COPOLYMER, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, ROSE FLOWER OIL, JUNIPERUS MEXICANA OIL, XANTHAN GUM, ETHYLHEXYL GLYCERIN, HYDROGENATED LECITHIN, CERAMIDE 3 (CERAMIDE NP), SUCROSE STEARATE, CHOLESTEROL, PALMITIC ACID, CHOLESTERYL MACADAMATE, SACCHARIDE ISOMERATE, HYDROLYZED LUPINE PROTEIN

Distributed by Humex, Inc.

505 Mercury Ln Ste B, Brea, CA 92821, USA

8 8890868206854



SUNSCREEN 100

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52554-1111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.26 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
JOJOBA OIL (UNII: 724GKU717M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
SQUALANE (UNII: GW89575KF9)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PROPANEDIOL (UNII: 5965N8W85T)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
HOUTTUYNIA CORDATA FLOWERING TOP (UNII: RH041UUZ22)	
ALUMINUM OXIDE (UNII: LM26O6933)	
GLYCERIN (UNII: PDC6A3C0OX)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DOCOSANOL (UNII: 9G1OE216XY)	
PURSLANE (UNII: M6S840WYG5)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	
ETHYLHEXYL TRIAZONE (UNII: XQN8R9SAK4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SACCHARIDE HYDROLYSATE (UNII: ED959S6ACY)	
CHIA SEED (UNII: NU0OLX06F8)	
TURMERIC (UNII: 856YO1Z64F)	
WATER (UNII: 059QF0KO0R)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
SUCROSE STEARATE (UNII: 274KW0O50M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52554-1111-2	1 in 1 PACKAGE	10/19/2017	
1	NDC:52554-1111-1	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	10/19/2017	

Labeler - CMS LAB Inc. (557795012)

Registrant - CMS LAB Inc. (557795012)

Establishment

Name	Address	ID/FEI	Business Operations
CMS LAB Inc.		557795012	relabel(52554-1111)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea Co., Ltd.		689512611	manufacture(52554-1111)

Revised: 10/2017

CMS LAB Inc.