

FUSION MINERAL BODY- zinc oxide lotion
ISDIN Corp.

Fusion Mineral Body

Drug Facts

Active Ingredient

Zinc Oxide 12%

Purpose

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 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

- Shake well before use
- apply liberally 15 minutes before sun exposure
- Reapply:
 - use a water-resistant sunscreen if swimming or sweating
 - at least every 2 hours.
- Children under 6 months of age: 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 broad spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit your time in the sun, especially from 10 a.m.- 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses.

Other Information

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

Inactive Ingredients

Allantoin, Aloe Barbadensis Leaf Juice Powder, Bisabolol, Butyloctyl Salicylate, Caprylic/Capric Triglyceride, Caprylyl Glycol, Ceteth-20, Cetyl Alcohol, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hexylene Glycol, Isoamyl Laurate, Jojoba Esters, Lecithin, Lysolecithin, Methylpropanediol, PEG-75 Stearate, Phenoxyethanol, Phenylpropanol, Polyglyceryl-2 Dipolyhydroxystearate, Pullulan, Pyrus Malus (Apple) Fruit Extract, Sclerotium Gum, Silica, Sodium Hydroxide, Squalane, Steareth-20, Tetrasodium Glutamate Diacetate, Tocopherol, Water, Xanthan Gum

Questions or comments?

Call (862) 242-8129 Monday – Friday (9 a.m. to 5 p.m. EST) or visit www.isdin.com

PRINCIPAL DISPLAY PANEL - 100 mL Tube Label

ISDIN
PHOTO

Fusion Mineral
BODY

BROAD SPECTRUM SPF 40

Ultralight protection and
hydration for all skin types

100% MINERAL
SUNSCREEN

3.4 FL OZ (100 mL)

ISDIN PHOTO

Fusion Mineral BODY

BROAD SPECTRUM SPF 40

Ultralight protection and
hydration for all skin types

100% MINERAL
SUNSCREEN

3.4 FL. OZ (100 mL)

XXXX

LOT:

MM-YYYY

EXP:

Drug Facts

Active Ingredient

Zinc Oxide 12%

Purpose

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 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 • Shake well before use • apply liberally 15 minutes before sun exposure • Reapply: • use a water-resistant sunscreen if swimming or sweating • at least every 2 hours. • Children under 6 months of age: 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 broad spectrum SPF value of 15 or higher and other sun protection measures including: • limit your time in the sun, especially from 10 a.m.- 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses.

Other Information • Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

Allantoin, Aloe Barbadensis Leaf Juice Powder, Bisabolol, Butyloctyl Salicylate, Caprylic/Capric Triglyceride, Caprylyl Glycol, Ceteth-20, Cetyl Alcohol, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hexylene Glycol, Isoamyl Laurate, Jojoba Esters, Lecithin, Lysolecithin, Methylpropanediol, PEG-75 Stearate, Phenoxyethanol, Phenylpropanol, Polyglyceryl-2 Dipolyhydroxystearate, Pullulan, Pyrus Malus (Apple) Fruit Extract, Sclerotium Gum, Silica, Sodium Hydroxide, Squalane, Steareth-20, Tetrasodium Glutamate Diacetate, Tocopherol, Water, Xanthan Gum

Questions or comments? Call (862) 242-8129 Monday – Friday (9 a.m. to 5 p.m. EST) or visit www.isdin.com

ESPACIO
RESERVADO
PARA
ETIQUETA
LOVE ISDIN
ref.190022289
IP FUSION
MINERAL BODY
SPF40 100ml

ISDIN® PHOTO Fusion Mineral
©2023 ISDIN S.A.
Manufactured for ISDIN
Corp, Morristown NJ 07960
Phone (862) 242-8129
www.isdin.com
Ref. 890027222
NDC 69494-014-02
190022272



8

FUSION MINERAL BODY

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69494-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	120 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
Hydrolyzed Jojoba Esters (Acid Form) (UNII: UDR641JW8W)	
Methylpropanediol (UNII: N8F53B3R4R)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Phenylpropanol (UNII: 0F897O3O4M)	
Xanthan Gum (UNII: TTV12P4NEE)	
Isoamyl Laurate (UNII: M1SLX00M3M)	
Hexylene Glycol (UNII: KEHOA3F75J)	
Tocopherol (UNII: R0ZB2556P8)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Glycerin (UNII: PDC6A3C0OX)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Water (UNII: 059QF0KO0R)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Ceteth-20 (UNII: I835H2IHHX)	
Pullulan (UNII: 8ZQ0AYU1TT)	
Squalane (UNII: GW89575KF9)	
Steareth-20 (UNII: L0Q8IK9E08)	
Cyclodextrins (UNII: 7E6SK9QDT8)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69494-014-02	100 mL in 1 TUBE; Type 0: Not a Combination Product	10/13/2023	
2	NDC:69494-014-01	250 mL in 1 TUBE; Type 0: Not a Combination Product	10/13/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M020	10/13/2023	

Labeler - ISDIN Corp. (079609155)

Revised: 10/2023

ISDIN Corp.