

LARKLY SPF30 MINERAL POWDER FACE SUNSCREEN- titanium dioxide and zinc oxide powder
LARKLY, 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.....Purpose

Titanium Dioxide 21.00%.....Sunscreen

Zinc Oxide 15.00%.....Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early 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
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients

Alpha-Tocopherol, Caprylic/Capric Triglyceride, Capryloyl Glycerin, Ceramide I, Ceramide II, Ceramide III, Ethylhexylglycerin, Fumed Silica, Glycyrrhiza Glabra, Green Tea Leaf, Iron Oxide Black, Iron Oxide Red, Iron Oxide Yellow, Kaolin, Magnesium Hydroxide, Maranta

Arundinacea Root, Mica, Glyceryl Caprylate, Glycerin, Caprylhydroxamic Acid, Resveratol, Sebacic Acid Copolymer, Tapioca Starch

Questions or Comments?

Call toll free: 1-888-426-4160



DIRECTIONS With the cap still on, hold the brush with the cap facing down and tap the brush a few times to evenly distribute minerals. Then remove the cap and run your finger through the bristles to ensure powder is flowing. Using small circular motions, sweep the brush over your skin including your face, neck, chest, the back of your hands & even your hair's part. Reapply at least every two hours for continued protection.

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**MINERAL POWDER
FACE SUNSCREEN**

Larkly
30
SPF



No Mess



Reef Safe



Sustainable
Ingredients

Drug Facts (continued)

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Manufactured for
LARKLY LCC
Marietta, GA 30067

0.21 oz | 6g

UVA / UVB protection
Broad Spectrum SPF 30



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LARKLYSUNCARE.COM

FBG927E

SUN CARE
Larkly
30
SPF

MINERAL
FACE
SUNSCREEN

Broad Spectrum SPF 30
UVA / UVB Protection

MINERAL POWDER
FACE SUNSCREEN

REFILL
Larkly
30
SPF

DIRECTIONS Simply twist and unscrew the bottom cartridge. Remove the lid from the new refill cartridge and replace.

Manufactured for
LARKLY LCC
Marietta, GA 30067

0.21 oz | 6 g

Drug Facts (continued)

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Inactive Ingredients

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Questions or Comments?
Call toll free: 1-888-426-4180

Drug Facts

Active Ingredients	Purpose
Titanium Dioxide 21%	Sunscreen
Zinc Oxide 15%	

Uses

- helps prevent sunburn
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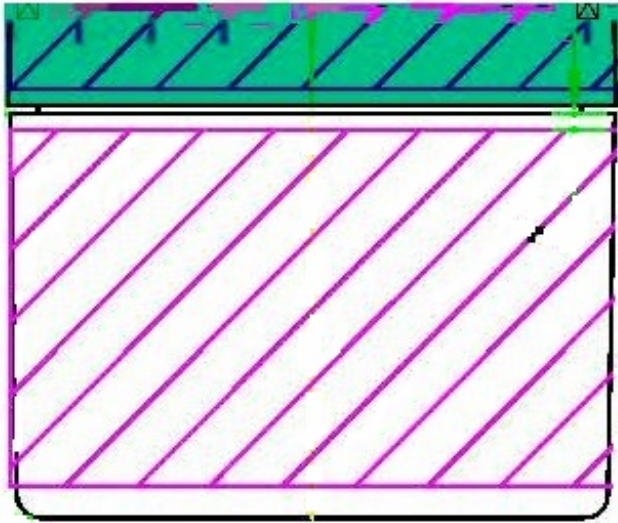
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LARKLYSUNCARE.COM

LEB0927D2



LARKLY SPF30 MINERAL POWDER FACE SUNSCREEN

titanium dioxide and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79287-0000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.212 kg in 1 kg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 kg in 1 kg

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
CERAMIDE 2 (UNII: C04977SRJ5)	
CERAMIDE 3 (UNII: 4370DF050B)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXAMETHYLDISILAZANE (UNII: H36C68P1BH)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
KAOLIN (UNII: 24H4NWX5CO)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
MARANTA ARUNDINACEA ROOT (UNII: FVN346W31A)	
MICA (UNII: V8A1AW0880)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
RESVERATROL (UNII: Q369O8926L)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79287-0000-2	1 in 1 BOX	07/10/2020	
1	NDC:79287-0000-1	0.006 kg in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product		
2	NDC:79287-0000-4	1 in 1 BOX	07/10/2020	
2	NDC:79287-0000-3	0.006 kg in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/10/2020	

Labeler - LARKLY, LLC (042886441)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(79287-0000)

Revised: 1/2023

LARKLY, LLC