

PERFECT MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream

SKIN PERFECT MEDICAL

Titanium Dioxide 8%

Zinc Oxide 3.8%

Sunscreen

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.

For external use only. Do not use on broken or damaged skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Keep out of reach of children.

Apply liberally 15 minutes before sun exposure. Use a water-resistant product 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.

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide (CI 77491), Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

- Protect this product from excessive heat and direct sun
- May stain some fabrics
- Cleanse thoroughly at nighttime
- PA+++

DRUG FACTS

ACTIVE INGREDIENTS:

Titanium Dioxide 8%

Zinc Oxide 3.8%

PURPOSE:

Sunscreen

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. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of the reach of children. If 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

• 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 am-2 pm

• Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide (CI 44791), Lauryl PEG/PPG-18/18 Hydrogen Dimethicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

OTHER INFORMATION:

• Protect this product from excessive heat and direct sun

• May stain some fabrics

• Cleanse thoroughly at nighttime

• PA +++

Skin Perfect Medical

skinperfectmedical.com

910 E Birch St, Suite 350, Brea, CA 92821

(714) 880-7888

87162-20350

SKIN
MEDICAL

PERFECT
MINERAL
SUNSCREEN

spf

broad spectrum
water resistant
(80 minutes)

1.8 oz

PERFECT MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:87162-203(NDC:58892-203)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	80 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	38 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CI 77491 (UNII: 1K09F3G675)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	

CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
CI 77492 (UNII: EX438O2MRT)	
ALUMINA (UNII: LMI26O6933)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CI 77499 (UNII: XM0M87F357)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87162-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/28/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/28/2018	

Labeler - SKIN PERFECT MEDICAL (088929175)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(87162-203)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(87162-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(87162-203)