

FOTO FACIAL AGE DELAY MATTE TINTED- titanium dioxide zinc oxide cream ADVANCED AESTHETIC DERMATOLOGY

ACTIVE INGREDIENTS

Titanium Dioxide 8% Zinc Oxide 3.8%

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 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.

WARNING

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS

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.

INACTIVE INGREDIENTS

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

OTHER INFORMATION

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

DRUG FACTS (cont)

• 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 Methicone, 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+++

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Foto Facial® Age Delay™
SKIN CARE PRODUCTS

**PHYSICAL SUN BLOCK
UV A & B PROTECTION
SPF 40 MATTE TINTED**

**Broad Spectrum
Water Resistant
(80 minutes)**

Net Wt. 1.8 oz / 53 g

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

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titanium dioxide zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:87197-203(NDC:58892-203)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients	
Ingredient Name	Strength
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CI 77491 (UNII: 1K09F3G675)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
ALUMINA (UNII: LMI26O6933)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CI 77499 (UNII: XM0M87F357)	
CI 77492 (UNII: EX438O2MRT)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87197-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/12/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/12/2020	

Labeler -
ADVANCED AESTHETIC DERMATOLOGY (090257273)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(87197-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(87197-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(87197-203)