

# **COMPLEXION PROTECTION MOISTURIZING SUNSCREEN- titanium dioxide cream**

**Hale Comeceuticals**

*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.*

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## **Complexion Protection Moisturizing Sunscreen**

### **Active Ingredients**

Titanium Dioxide 7.5%

### **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.

### **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 reach of children**

If swallowed, get medical help or contact a poison Control Center right away.

### **Inactive Ingredients**

Alumina, Borago Officinalis Seed Oil, Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetareth-20, Catearyl Alcohol, Cetyl Alcohol, Disodium EDTA, Glycerin, Glyceryl Stearate, Hydrogenated Vegetable Oil, Olea Europaea (Olive) Fruit Oil, PEG-100 Stearate, Phenoxyethanol, Polyhydroxystearic Acid, Squalane, Sodium Hyaluronate, Sorbic Acid, Stearic Acid, Tocopheryl Acetate, Urea, Water, Xanthan Gum.

## **Directions**

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- reapply :
  - after 40 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 a.m. - 2 p.m.
  - wear long-sleeved shirts, pants, hats, and sunglasses
  - children under 6 months: Ask a doctor.

## **Other Information**

- protect this product from excessive heat and direct sun
- may stain some fabrics.

## **Questions or comments?**

Scan the QR Code below,

visit **[www.halecosmeceuticals.com](http://www.halecosmeceuticals.com)**,

or call toll-free **800-951-7005**.

## **Package Labeling**

# Hale Cosmeceuticals

## Complexion Protection

Moisturizing Sunscreen

Broad Spectrum  
SPF 35+ Sunscreen

2.5 FL OZ (74 mL)

### Drug Facts

Active Ingredients	Purpose
Titanium Dioxide 7.5 %	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 reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Inactive Ingredients** • Alumina, Borago Officinalis Seed Oil, Capric/Caprylic Triglyceride, Caprylyl Glycol, Cetearth-20, Cetearyl Alcohol, Cetyl Alcohol, Disodium EDTA, Glycerin, Glyceryl Stearate, Hydrogenated Vegetable Oil, Olea Europaea (Olive) Fruit Oil, PEG-100 Stearate, Phenoxyethanol, Polyhydroxystearic Acid, Squalane, Sodium Hyaluronate, Sorbic Acid, Stearic Acid, Tocopheryl Acetate, Urea, Water, Xanthan Gum.

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Dist. by Hale Cosmeceuticals Bloomington, IL 61704  
H134.025.01



## COMPLEXION PROTECTION MOISTURIZING SUNSCREEN

titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71987-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	75 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>BORAGE SEED OIL</b> (UNII: F8XAG1755S)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>UREA</b> (UNII: 8W8T17847W)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71987-001-00	74 mL in 1 TUBE; Type 0: Not a Combination Product	01/09/2018	12/31/2024

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/09/2018	12/31/2024

**Labeler** - Hale Comeceuticals (168405822)