

COMPLEXION PROTECTION- 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.

Complexion Protection 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, Capric/Caprylic Triglyceride, Caprylyl Glycol, Ceteareth-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**,

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

Package Labeling

Hale Cosmeceuticals



1 FL OZ (30 mL)

Do not use if seal around cap is broken or missing.

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.	
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.	
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Inactive Ingredients • Alumina, Borago Officinalis Seed Oil, Capric/Caprylic Triglyceride, Caprylyl Glycol, Ceteareth-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.	
Questions or comments? Visit www.halecosmeceuticals.com or call toll-free (800) 951-7005.	

Manufactured for Hale Cosmeceuticals • Bloomington, IL 61704
H134.01.03 • Lot# H172104 • Exp: 2018/04

COMPLEXION PROTECTION

titanium dioxide cream				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71987-000	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	75 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALUMINUM OXIDE (UNII: LMI26O6933)				
BORAGE SEED OIL (UNII: F8XAG1755S)				
CAPRYLYL GLYCOL (UNII: 00YIU5438U)				
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)				
GLYCERIN (UNII: PDC6A3C0OX)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
PEG-100 STEARATE (UNII: YD01N1999R)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
SQUALANE (UNII: GW89575KF9)				
HYALURONATE SODIUM (UNII: YSE9PPT4TH)				
SORBIC ACID (UNII: X045WJ989B)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
UREA (UNII: 8W8T17847W)				
WATER (UNII: 059QF0KO0R)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71987-000-00	30 mL in 1 BOTTLE, GLASS; 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)

Revised: 12/2022

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