

**HALE COSMECEUTICALS COMPLEXION PROTECTION SUNSCREEN SPF 35-
titanium dioxide cream
Hale Cosmeceuticals, Inc.**

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.

Hale Cosmeceuticals Complexion Protection Sunscreen SPF 35

Drug Facts

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.

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

- immediately after towel drying
- at least every 2 hours
- children under 6 months: Ask a doctor

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

Other Information

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

Inactive Ingredients

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

Questions or comments?

Visit www.halecosmeceuticals.com or call toll-free (800) 951-7005.

Package Labeling:30ml



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

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Titanium Dioxide 7.5%	Sunscreen
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Questions or comments? Visit www.halecosmeceuticals.com or call toll-free (800) 951-7005.	
Manufactured for Hale Cosmeceuticals • Bloomington, IL 61704 H134.01.04 • Lot# H192305 • Exp: 2021/05	

Package Labeling:74ml

Hale Cosmeceuticals



Complexion Protection Sunscreen

SPF 35

2.5FL OZ (74 mL)

Drug Facts

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Titanium Dioxide 7.5%	Sunscreen

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Questions or comments?

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Manufactured for Hale Cosmeceuticals • Bloomington, IL 61704
H134.01.04 • Lot# H170704 • Exp: 2019/04

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

HALE COSMECEUTICALS COMPLEXION PROTECTION SUNSCREEN SPF 35

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71987-008
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
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
SQUALANE (UNII: GW89575KF9)	
BORAGO OFFICINALIS SEED (UNII: 2GXJ790US0)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

PEG-100 STEARATE (UNII: YD01N1999R)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
GLYCERIN (UNII: PDC6A3C0OX)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
SORBIC ACID (UNII: X045WJ989B)
OLIVE OIL (UNII: 6UYK2WLWLE)
TOCOPHEROL (UNII: ROZB2556P8)
UREA (UNII: 8W8T17847W)
CETYL ALCOHOL (UNII: 936JST6JCN)
XANTHAN GUM (UNII: TTV12P4NEE)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71987-008-01	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	12/01/2020	12/31/2024
2	NDC:71987-008-02	74 mL in 1 TUBE; Type 0: Not a Combination Product	12/01/2020	12/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/01/2020	12/31/2024

Labeler - Hale Cosmeceuticals, Inc. (168405822)

Revised: 12/2022

Hale Cosmeceuticals, Inc.