

COMPLEXION PERFECTION BB- 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 Perfection BB Cream

Active Ingredients

Titanium Dioxide 5.0%

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, Cetearyl Alcohol, Disodium EDTA, Glycerin, Glyceryl Caprylate, Glyceryl Stearate, Hydrogenated Vegetable Oil, Hydroxypropyl Cyclodextrin, Iron Oxide CI-77492, Iron Oxide CI-77499, Iron Oxide CI-77491, Kojic Dipalmitate, Niacinamide, Olea Europaea (Olive) Fruit Oil, Palmitoyl Tripeptide-38, PEG-100 Stearate, Phenoxyethanol, Polyglyceryl-2 Caprate, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hyaluronate, Sorbic Acid, Squalane, Stearic Acid, Sucrose Stearate, Titanium Dioxide CI-77891,

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.

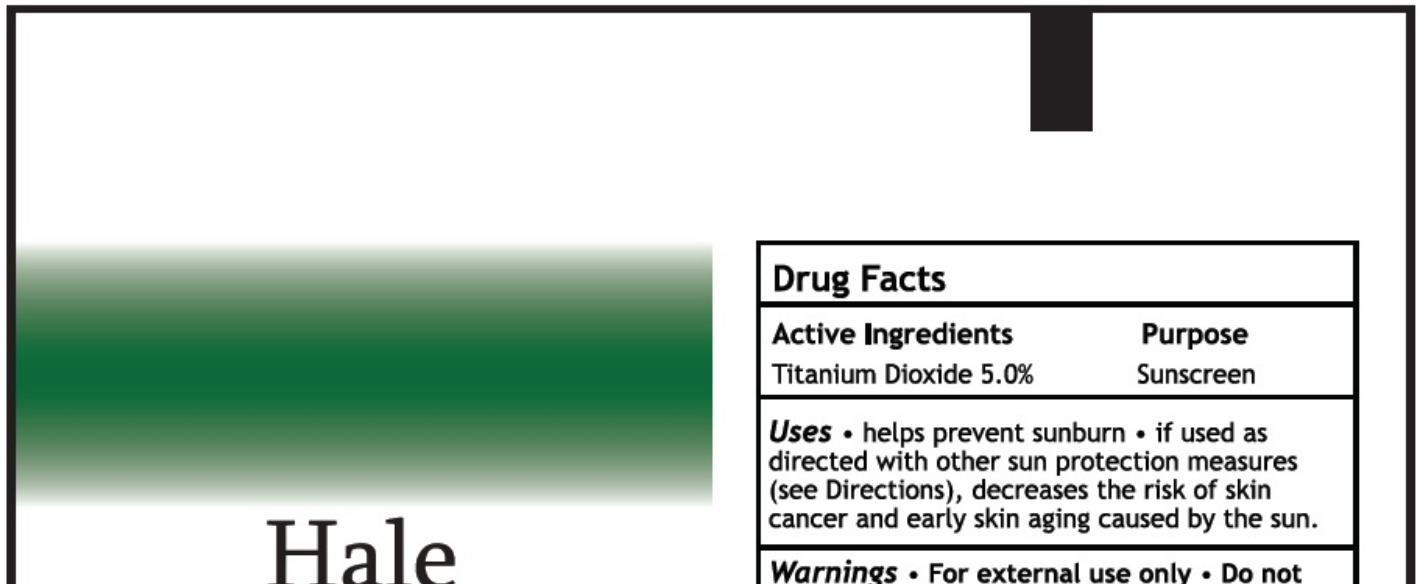
Questions or comments?

Scan the QR Code below,

visit www.halecosmeceuticals.com,

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

Package Labeling



Drug Facts	
Active Ingredients	Purpose
Titanium Dioxide 5.0%	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	

Cosmeceuticals

Complexion Perfection BB Cream

Sunscreen

**Broad Spectrum
SPF 20+**

1.0 FL OZ (30 mL)

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, Cetearyl Alcohol, Disodium EDTA, Glycerin, Glyceryl Caprylate, Glyceryl Stearate, Hydrogenated Vegetable Oil, Hydroxypropyl Cyclodextrin, Iron Oxide CI-77492, Iron Oxide CI-77499, Iron Oxide CI-77491, Kojic Dipalmitate, Niacinamide, Olea Europaea (Olive) Fruit Oil, Palmitoyl Tripeptide-38, PEG-100 Stearate, Phenoxyethanol, Polyglyceryl-2 Caprate, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hyaluronate, Sorbic Acid, Squalane, Stearic Acid, Sucrose Stearate, Titanium Dioxide CI-77891, Tocopheryl Acetate, Urea, Water, Xanthan Gum.

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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.

Dist. by: Hale Cosmeceuticals Bloomington, IL 61704
H135.01.01



COMPLEXION PERFECTION BB

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71987-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
BORAGE SEED OIL (UNII: F8XAG1755S)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
KOJIC DIPALMITATE (UNII: 13N249RWTM)	
NIACINAMIDE (UNII: 25X5118RD4)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PALMITOYL LYSYLDIOXYMETHIONYLLYSINE (UNII: T7A529FB8O)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
JOJOBA OIL (UNII: 724GKU717M)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SORBIC ACID (UNII: X045WJ989B)	
SQUALANE (UNII: GW89575KF9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE STEARATE (UNII: 274KW0050M)	
.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:71987-002-00	30 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)

Revised: 12/2022

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