

HARKEN DERM HIGH PERFORMANCE SUNSCREEN- titanium dioxide, zinc oxide lotion
Harken Derm LLC

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.

Harken Derm High Performance Sunscreen

Active ingredients

Titanium Dioxide 4.8%

Zinc Oxide 9.3%

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 product is 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 two 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

Cyclomethicone 5, Water, Dimethicone Crosspolymer (450000 MPA.S At 12% In Cyclopentasiloxane), Butylene Glycol, Cetyl PEG/PPG-10/1 Dimethicone (HLB 2), Polymethylsilsesquioxane (4.5 Microns), Caprylyl Trisiloxane, PEG-10 Dimethicone (600 CST), Argan Oil, Glycerin, Distearidimonium Hectorite, Isododecane, .ALPHA.- Tocopherol Acetate, Aluminum Oxide, Apple, Caprylyl Glycol, Ethylhexylglycerin, Helianthus Annuus Flowering Top, Hexylene Glycol, Lauryl Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Levomenol, Methicone (20 CST), PEG/PPG-18/18 Dimethicone, Phenoxyethanol, Propylene Carbonate, Rice Bran, Rosemary, Silicon Dioxide, Sodium Chloride, Tocopherol, Triethoxycaprylylsilane.

Other information

- protect the product in this container from excessive heat and direct sun

Questions?

Please visit **harkenderm.com** or call toll-free **(833) Dr H Derm** or (833-374-3376)

Harken Derm High Performance Sunscreen Principal Display Panel



HARKEN®

DERM

**50 HIGH PERFORMANCE
SUNSCREEN**

- Broad Spectrum SPF 50
- Non-Greasy 100% Mineral Formula with Antioxidants
- Provides Superior UVA / UVB Protection

WATER RESISTANT (80 MINUTES)

SWEAT RESISTANT

Created by Dermatologists

To Keep You Covered in the Toughest Conditions

Reef-friendly = Chemical Filter-free = Fragrance-free = For All Skin Types

Made in USA
3.4 fl oz (100 ml)

HARKEN DERM HIGH PERFORMANCE SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71892-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.048 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.093 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERIN (UNII: PDC6A3C0OX)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
ISODODECANE (UNII: A8289P68Y2)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
RICE BRAN (UNII: R60QEP13IC)	
ROSEMARY (UNII: IJ67X351P9)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONE CROSSPOLYMER (45000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
ALUMINUM OXIDE (UNII: LM26O6933)	
APPLE (UNII: B423VGH5S9)	
ARGAN OIL (UNII: 4V59G5UW9X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
LEVOMENOL (UNII: 24WE03BX2T)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71892-000-00	100 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2018	07/31/2020

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2018	07/31/2020

Labeler - Harken Derm LLC (080891015)

Revised: 12/2018

Harken Derm LLC