

BROAD SPECTRUM SPF45- zinc oxide, octinoxate gel
Drmtlgy, LLC

DRMTLGY® Broad Spectrum SPF45

Drug Facts

Active ingredients

Zinc Oxide 12%

Octinoxate 7.5%

Purpose

Sunscreen

Uses

Helps prevent sunburn. • If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only.

When using this product • keep out of eyes. Rinse with water to remove. Stop use and ask physician if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Apply to face and neck, avoiding the eye area. Wait at least 30 minutes before sun exposure, or as directed by a physician. Reapply at least every 2 hours.

Precautions

• 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 value of SPF 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 of age: Ask a physician.

Inactive Ingredients:

Water, Cyclopentasiloxane, Niacinamide, Oleth-3 Phosphate, Octyldodecyl Neopentanoate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyisobutene, PEG-7 Trimethylolpropane Coconut Ether, Glycerin, Tocopheryl Acetate, Polygonum Aviculare Extract, Sodium Hyaluronate, Disodium EDTA, Sodium Hydroxide, Citric Acid, Phenoxyethanol, Ethylhexylglycerin, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Triethoxycaprylsilane

Questions or comments?

1-888-DRMTLGY

MEDICAL GRADE SKIN CARE

PROTECT

defend//prevent

Broad Spectrum
UVA/UVB Protection

Dist. by DRMTLGY, LLC
Chatsworth, CA 91311
www.DRMTLGY.com

Made in USA

Packaging

DRMTLG^Y
MEDICAL GRADE SKIN CARE

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SPECTRUM SPF45

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1.7 fl oz / 50 mL

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BROAD SPECTRUM SPF45

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83286-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	12 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
PEG-7 TRIMETHYLOLPROPANE COCONUT ETHER (UNII: MVJ3AD73GG)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83286-014-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/01/2025	

Labeler - Drmtlgy, LLC (094762235)