

**BROAD SPECTRUM SPF45- zinc oxide, octinoxate gel**  
**Neutraderm, 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.*

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**Broad Spectrum SPF45**

***Drug Facts***

***Active ingredient***

Zinc Oxide 12%

Octinoxate 7.5%

***Purpose***

Sunscreen

***Use*** 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 after 80 minutes of swimming or sweating. Reapply immediately after towel drying 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, Triethoxycaprylylsilane

**DRMTLGY®**

**MEDICAL GRADE SKIN CARE**

Anti-Aging

Protects Against UV Rays

High Purity

Niacinamide and Hyaluronic Acid

Transparent Zinc Oxide

DRMTLGY, LLC

Chatsworth, CA

www.DRMTLGY.com

Made In USA

Packaging

DRMTLGY<sup>®</sup>  
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Broad  
Spectrum  
SPF45

Anti-Aging

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2 oz / 57 g

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N-1161



DRMTLGY, LLC  
Chatsworth, CA  
www.DRMTLGY.com

**BROAD SPECTRUM SPF45**

zinc oxide, octinoxate gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:39765-035
<b>Route of Administration</b>	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 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:39765-035-01	57 g in 1 BOTTLE; Type 0: Not a Combination Product	01/06/2020	

### Marketing Information

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

**Labeler** - Neutraderm, Inc. (146224444)

### Establishment

Name	Address	ID/FEI	Business Operations

