

EGF UV SHIELD- octinoxate cream
Dermaesthetics 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.

EGF UV Shield

Drug Fact

Active ingredient

Octinoxate 7.50%
Octisalate 5.00%
Zinc Oxide 4.90%
Titanium Dioxide 4.15%
Amiloxate 2.00%

Purpose

Sunscreen

Keep out of reach of children

Stop use and ask a doctor

if rash or irritation develops and lasts.

Keep out of reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

Indication & usage

Directions

Apply generously and evenly 15-20 minutes before sun exposure.

Use a water resistant sunscreen if swimming or sweating.

Reapply every 1-2 hours after towel drying, swimming or perspiring.

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 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-sleeve shirts, pants, hats, and sunglasses

Children under 6 months: Ask a doctor

Warning

Warnings

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 prevent sunburn, not skin cancer or early skin aging.

For external use only.

Do not use on damaged or broken skin. If sun irritation develops or increases.

When using this product keep out of eyes. Rinse with water to remove.

Dosage & administration

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.

Inactive ingredient

Water, Propylene Glycol, Cyclopentasiloxane, Cyclohexasiloxane, Hydrogenated Poly(C6-14 Olefin), Cetyl PEG/PPG-10/1 Dimethicone, PEG-10 Dimethicone, Betaine, Disteardimonium Hectorite, Magnesium Sulfate, Sorbitan Sesquioleate, Aluminum Hydroxide, Stearic Acid, Dimethicone/Vinyl Dimethicone Crosspolymer, Silica, Methyl Methacrylate Crosspolymer, Triethoxycaprylylsilane, Portulaca Oleracea Extract, Poncirus Trifoliata Fruit Extract, Tocopheryl Acetate, Sorbitan Isostearate, Squalane, Simmondsia Chinensis(Jojoba) Seed Oil, Macadamia Ternifolia Seed Oil, Diospyros Kaki Leaf Extract, Cinnamomum Cassia Bark Extract, Artemisia Princeps Leaf Extract, Chrysanthellum Indicum Extract, Chaenomeles Sinensis Fruit Extract, Camellia Sinensis Leaf Extract, Aloe Barbadosis Leaf Juice, Chamomilla Recutita(Matricaria) Flower Extract, Lecithin, Sorbitol, Xanthan Gum, Glyceryl Linoleate, Glyceryl Linolenate, rh-Oligopeptide-1, Acetyl Hexapeptide-8, Sodium Ascorbate, Retinyl Palmitate, Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Fragrance

EGF UV Shield

EGF UV Shield

Net WT. 2.03 fl. oz(60ml)

Drug Facts		
Active ingredient		Purpose
Octinoxate	7.50%	Sunscreen
Octisalate	5.00%	Sunscreen
Zinc Oxide	4.90%	Sunscreen
Titanium Dioxide	4.15%	Sunscreen
Amiloxate	2.00%	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 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 prevent sunburn, not skin cancer or early skin aging		
For external use only		

Do not use on damaged or broken skin. If sun irritation develops or increases.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash or irritation develops and lasts

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

Directions

- Apply generously and evenly 15-20 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply every 1-2 hours after towel drying, swimming or perspiring.
- **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 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-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

Other information

- Protect this product from excessive heat and direct sun. Store below 30°C

Inactive ingredients

Water, Propylene Glycol, Cyclopentasiloxane, Cyclohexasiloxane, Hydrogenated Poly(C6-14 Olefin), Cetyl PEG/PPG-10/1 Dimethicone, PEG-10 Dimethicone, Betaine, Disteardimonium Hectorite, Magnesium Sulfate, Sorbitan Sesquioleate, Aluminum Hydroxide, Stearic Acid, Dimethicone/Vinyl Dimethicone Crosspolymer, Silica, Methyl Methacrylate Crosspolymer, Triethoxycaprylylsilane, Portulaca Oleracea Extract, Poncirus Trifoliata Fruit Extract, Tocopheryl Acetate, Sorbitan Isostearate, Squalane, Simmondsia Chinensis (Jojoba) Seed Oil, Macadamia Ternifolia Seed Oil, Diospyros Kaki Leaf Extract, Cinnamomum Cassia Bark Extract, Artemisia Princeps Leaf Extract, Chrysanthellum Indicum Extract, Chaenomeles Sinensis Fruit Extract, Camellia Sinensis Leaf Extract, Aloe Barbadosensis Leaf Juice, Chamomilla Recutita (Matricaria) Flower Extract, Lecithin, Sorbitol, Xanthan Gum, Glyceryl Linoleate, Glyceryl Linolenate, rh-Oligopeptide-1, Acetyl Hexapeptide-8, Sodium Ascorbate, Retinyl Palmitate, Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Fragrance

Questions or comments? [1-562-408-4567](tel:1-562-408-4567)

■ **Manufactured by:** EYESOME CO., LTD

■ **Distributed by:** DERMAESTHETICS BEVERLY HILLS FORMULA OF U.S.A INC.
16300 DOWNEY AVE. PARAMOUNT, CA 90723

EGF UV SHIELD

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58831-1001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 60 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 60 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 60 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.15 g in 60 g
AMILOXATE (UNII: 376KTP06K8) (AMILOXATE - UNII:376KTP06K8)	AMILOXATE	2 g in 60 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 3) (UNII: G300307ZXP)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
BETAINE (UNII: 3SCV180C9W)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
PURSLANE (UNII: M6S840WGX5)	
PONCIRUS TRIFOLIATA FRUIT (UNII: 44445L49J2)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SORBITAN ISO STEARATE (UNII: 01S2G2C1E4)	
SQUALANE (UNII: GW89575KF9)	
JOJOBA OIL (UNII: 724GKU717M)	
MACADAMIA OIL (UNII: 515610SU8C)	
DIOSPYROS KAKI LEAF (UNII: Q71GF9OBNO)	
CHINESE CINNAMON (UNII: WS4CQ062KM)	
ARTEMISIA PRINCEPS LEAF (UNII: SY077EW02G)	
CHRYSANTHELLUM INDICUM TOP (UNII: STJ856D1Z0)	
CHAENOMELES SINENSIS FRUIT (UNII: 6S5Q1Q537Z)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHAMOMILE (UNII: FGL3685T2X)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERYL MONOLINOLEATE (UNII: 4763AXI84L)	
GLYCERYL LINOLENATE (UNII: SGB6X4G86K)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWIL)	
SODIUM ASCORBATE (UNII: S033EH8359)	

VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

METHYLPARABEN (UNII: A2I8C7HI9T)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

BUTYLPARABEN (UNII: 3QPIIU3FV8)

Product Characteristics

Color	white (silver)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58831-1001-2	1 in 1 BOX	12/01/2018	
1	NDC:58831-1001-1	60 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/26/2013	

Labeler - Dermaesthetics Inc. (688384549)

Registrant - Dermaesthetics Inc. (688384549)

Establishment

Name	Address	ID/FEI	Business Operations
Eyesome Co Ltd		557795360	manufacture(58831-1001)

Establishment

Name	Address	ID/FEI	Business Operations
Dermaesthetics Inc.		688384549	relabel(58831-1001)

Revised: 12/2019

Dermaesthetics Inc.