EGF UV SHIELD- oxtinoxate 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

for external use only

Inactive ingredient

Water, Propylene Glycol, Cyclopentasiloxane, Hydrogenated Poly(C6-14 Olefin Polymer), pentylent glycol, Cetyl PEG/PPG-10/1 Dimethicone, PEG-10 Dimethicone, Betaine, Magnesium Sulfate, Disteardimonium Hectorite, Sorbitan Sesquioleate, butylene glycol, Aluminum Hydroxide, Stearic Acid, silica Dimethicone/Vinyl Dimethicone Crosspolymer, Methyl Methacrylate Crosspolymer, caprylyl glycol, tocopheryl acetate, Triethoxycaprylylsilane, Portulaca Oleracea Extract, Poncirus Trifoliata Fruit Extract, Tocopheryl Acetate, jojoba seed oil, ethyhexylglycerin, Aloe Barbadensis Leaf Juice, squalane, sorbitan isostearate, chamomilla recutita (matricaria) flower extract, macadamia ternifolia seed oil, rh-oligopeptide-1, chaenomeles sinensis fruit extract, cinnamomum cassia bark extract, diospyros kaki leaf extract, artemisia princeps leaf extract, sorbitol, camellia sinensis leaf extract, glycerin, chrysanthellum indicum extract, lecithin, glyceryl linoleate, glyceryl linolenate, phenoxyethano, xanthan gum, acetyl hexapeptide-8, sodium ascorbyl phosphate, retinyl palmitate, disodium edta, glyceryl caprylate, fragrance



SPF 50+ & PA+++

Drug Facts

Active Ingredients Purpose
Octinoxate 7.50% Sunscreen

Octisalate 5,00% Sunscreen
Zinc Oxide 4,90% Sunscreen
Titanium Dioxide 4,15% Sunscreen
Amiltoxate 2,00% Sunscreen

Uses: Helps prevent sunburn If used as directed other sul protection measures (see directions), decreases the risk of skir cancer and early skin aging caused by the sun.

Warnings

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For external use only

Do not use on damaged or broken skir

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 Poleon Control Center (lot) sway

Directions

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 Use a water resistant sunscreen if swimming or sweating.
 Reapply every 1-2 hours after towel drying, swimming or perspirin.
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 wear long sleeve shirts, pants, hats, and su Children under 6 months: Ask a doctor

Other Information

Protect this product from excessive heat and direct sun. Store selow 30 degrees C.

Inactive Ingredients Water, Cyclohexaeiloxane, Propylene Glycol, Hydrogenated C8-14 Olefin Polymer, Pertylene Glycol Cetyl PEG/PPG-10/I Dimethicone, PEG-10 Dimethicone, Betaine Magnesium Sulfate, Disteractimonium Hectoriris, Sortian Seegui-cleate, Butylene Glycol, Aluminum Hydroxide, Stearic Acid, Silca, Methyl Methacrylate Crosspolymer, Dimethicone Crosspolymer, Capyly Glycol, Tocopheryl Acetate, Triethoxycaprylylainer, Poncius Infoliata Fruit Extract, Portulaca Olerace Extract Simmondsia Chinensis (Jojoba) Seed Oli, Ethylhexylgytorin, Aloe Barbadensis Leef Juice, Squalarie, Sortian Insotearate, Chamomilia Recutita (Matricaria) Rower Extract, Macadamia Ternifolia Seed Oli, rhollogoepilder-1, Cheanomeles Sinensis Fruit Extract, Chinemomum Cassis Bark Extract, Diospyros Kaki Leef Extract, Aremie-ia Princept Leef Extract, Sorbirol, Camellia Sinensis Leef Extract, Glycerin, Chrysanthelum Indicum Extract, Locibin, Glycoryl Linolenske, Glycoryl

Questions or Comments? (562) 408-4567

Manufactured by: Eyesome Co. LTD
Distributed by: Dermaesthetics Beverly Hills Formula USA, Inc.
16300 Downey Ave. Paramount. CA USA 90723

vw.dermaestneticsusa.co www.dermaes.co

Professional Formula

> UV SHIELD Regulating Care

> > 50 SPF 50+

DBH DERMÆSTHETICS BEVERLY HILLS, USA

For all Skin types.
Daily protection and moisturizer
60ml / 2.03 fl.oz.





EGF UV SHIELD

oxtinoxate cream

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:58831-2001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.9 g in 100 mL	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	4.15 g in 100 mL	

AMILOXATE

2 g in 100 mL

Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)

TRIEPO XYCYCLO HEXASILANE (UNII: 066Q83563R)

Packaging

# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:58831-2001-1	60 mL in 1 TUBE; Type 0: Not a Combination Product	07/07/2018	

Marketing Information

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

Labeler - Dermaesthetics Inc. (688384549)

Registrant - Dermaesthetics Inc. (688384549)

Establishment

Name	Address	ID/FEI	Business Operations
Eyesome Co Ltd		557795360	manufacture (58831-2001)

Establishment

Establishment				
Name	Address	ID/FEI	Business Operations	
Dermaesthetics Inc.		688384549	relabel(58831-2001)	

Revised: 12/2019 Dermaesthetics Inc.