

SPF RX - ULTRA-CLEAR DAILY SKIN HYDRATOR SPF 50- zinc oxide, octinoxate cream
Cal Pharma 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.

ACTIVE INGREDIENTS

Zinc Oxide 9%

Octinoxate 7.5%

Purpose

Sunscreen

USES

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer, early skin aging by the sun.

INDICATION

SPF RX's Ultra-Clear Skin Hydrator sets a new standard in healthy skin and nourishing skin protection. It is a zinc-based broad spectrum sunscreen that not only protects against UVA and UVB rays, it has Liposhield® to shield your skin from the high energy visible light from smartphones, computer screens and other indoor light sources. Professional strength skin calming and nourishing moisture: Ultra-Clear Daily Skin Hydrator is actually a multi-functional facial product that also nourishes and hydrates your skin with a potent blend of hyaluronic acid and pure ceramides.

WARNINGS

For external use only. Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs.

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
- At least every 2 hours. Immediately after towel drying.

Sun Protection Measures: Spending time in the sun increases your risk of skin cancer & 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.

INACTIVE INGREDIENTS

Water, Cyclopentasiloxane, PEG-10 Dimethicone, Methicone, Isododecane, Propanediol, Caprylic/Capric Triglycerides, Isodecyl Neopentanoate, Dimethicone/bis-Isobutyl PPG-20 Crosspolymer, Stearyl/Octyldodecyl Citrate Crosspolymer, Tapioca Starch, Polymethylsilsesquioxane, Glycerin, Isostearic Acid, Polyhydroxystearic Acid, Dimethicone, Phenoxyethanol, Benzoic Acid, Ethylhexylglycerin, Glycereth-2 Cocoate, Dicaprylyl Ether, Dehydroxanthan Gum, Carthamus Tinctorius Seed Oil, Melanin, Sodium Hyaluronate, Silicon Dioxide, Tocopheryl Acetate, Dipotassium Glycyrrhizinate, Porphyridium Cruentum Extract, Eucalyptus Globulus Leaf Extract, Zingiber Officinale Root Extract, Gaultheria Procumbens Leaf Extract, Avena Sativa Kernel Extract, Allantoin, Ceramide 3

OTHER INFORMATION

Protect this product from excessive heat and direct sun.

Drug Facts

ACTIVE INGREDIENTS

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Octinoxate 7.5% } Sunscreen

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mer, Octyldodecyl Stearyl Citrate Crosspolymer, Tapioca Starch, Polymethylsilsesquioxane, Glycerin, Isostearic Acid, Polyhydroxystearic Acid, Dimethicone, Isododecane, Dimethicone/bis-Isobutyl PPG-20 Crosspolymer, Phenoxyethanol, Benzoic Acid, Ethylhexylglycerin, Glycereth-2 Cocoate, Dicaprylyl ether, Dehydroxanthan Gum, Carthamus Tinctorius (Safflower) Seed Oil, Melanin [Defends against HEV Light/Anti-Aging], Sodium Hyaluronate Acid

[Moisturizing Agent], Trimethylated Silica Gel, Tocopheryl Acetate (Vitamin E Acetate) [Antioxidant] Dipotassium Glycyrrhizinate [Moisturizing/Skin Conditioning Agent; Anti-Inflammatory /Anti-Allergic Properties], Porphyridium cruentum, Eucalyptus Globulus Leaf Extract [Anti-Inflammatory Blend] Zingiber Officinale (Ginger) Root Extract [Anti-Inflammatory Blend] Gaultheria Procumbens (Wintergreen) Leaf Extract [Anti-Inflammatory Blend] Avena Sativa (Oat) Kernel Extract [Anti-Inflammatory Blend] Allantoin [Anti-Inflammatory Blend] Ceramide 3 [Moisturizing Agent]

Indication: SPF Rx's Ultra-Clear Skin Hydrator sets a new standard in healthy skin and nourishing skin protection. It is a zinc-based broad spectrum sunscreen that not only protects against UVA and UVB rays, it has Liposheild® to shield your skin from the high energy visible light from smartphones, computer screens and other indoor light sources Professional strength skin calming and nourishing moisture: Ultra-Clear Daily Skin Hydrator is actually a multi-functional facial product that also nourishes and hydrates your skin with a potent blend of hyaluronic acid and pure ceramides.

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Manufactured By:



www.cal-pharma.com



ULTRA-CLEAR[®]
DAILY SKIN
HYDRATOR

Mineral-Based
Broad Spectrum

SPF 50

• CALM, HYDRATE, PROTECT

• WATER RESISTANT (80 MINUTES)

• NO FRAGRANCE, NO OXYBENZONE,
NO PABA, NO WHITE FILM

SPF Rx
YOUR PRESCRIPTION FOR
SUNSCREEN NATURALLY

SPF RX - ULTRA-CLEAR DAILY SKIN HYDRATOR SPF 50

zinc oxide, octinoxate cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:55628-8585

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	9 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: 0THT5PCI0R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
ISODODECANE (UNII: A8289P68Y2)	
PROPANEDIOL (UNII: 5965N8W85T)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
DIMETHICONE/BIS-ISOBUTYL PPG-20 CROSSPOLYMER (UNII: O4I3UFO6ZF)	
OCTYLDODECYL STEARATE (UNII: K6F16QGO28)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	
POLYMETHYLSILSESQUOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
DEHYDROXANTHAN GUM (UNII: 63ZP7IIBQO)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
MELANIN SYNTHETIC (TYROSINE, PEROXIDE) (UNII: O0CV1RMR44)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
PORPHYRIDIUM PURPUREUM (UNII: K2P8K2558N)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
GINGER (UNII: C5529G5JPQ)	
GAULTHERIA PROCUMBENS LEAF (UNII: 2125M16OWN)	
OAT (UNII: Z6J799EAJK)	
ALLANTOIN (UNII: 344S277G0Z)	
CERAMIDE 3 (UNII: 4370DF050B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55628-8585-0	8 g in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/31/2017	

Labeler - Cal Pharma LLC (078721283)

Registrant - Cal Pharma LLC (078721283)

Establishment

Name	Address	ID/FEI	Business Operations
Health Specialty		794053863	manufacture(55628-8585)

Revised: 7/2017

Cal Pharma LLC