

EPIONCE ULTRA SHIELD- homosalate, octisalate, zinc oxide lotion
Episciences, 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.

Epionce Ultra Shield SPF 50

Active ingredients

Homosalate 9.95%

Octisalate 5.0%

Zinc Oxide 10.1%

Purpose

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

For external use only

Do not use

- on damaged or broken skin

Stop use and ask a doctor if

- rash occurs

When using this product

- keep out of eyes.
Rinse with water to remove.

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
 - immediately after towel drying
 - at least every two hours
- children under 6 months: Ask a doctor
- **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 value 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-sleeved shirts, pants, hats and sunglasses

Other information

- protect this product from excessive heat and direct sun

Inactive ingredients

Alkyl (C12-15) Benzoate, Ammonium Acryloyldimethyltaurate/VP Copolymer, Butylene Glycol, Caprylyl Glycol, Caprylyl Trisiloxane, Cetostearyl Alcohol, Date, Dimethicone, Ethylhexylglycerin, Glycerin, Hexylene Glycol, Hydrogenated Polybutene (1300 MW), Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (4500 MPA.S AT 1%), Linseed Oil, Malic Acid, Meadowfoam Seed Oil, Phenoxyethanol, Polyhydroxystearic Acid (2300 MW), Polysorbate 80, Safflower Oil, Steareth-2, Steareth-21, Triethoxycaprylylsilane, Trimethylsiloxysilicate (M/Q 0.66), Water.

Questions?

Call toll free **1-866-374-6623**

Principial Display Panel

Protect & Prevent



epionce[®]
We Deliver the Beauty of Healthy Skin™

Ultra Shield SPF 50
Lotion ultra-protectrice

SUNSCREEN

BROAD SPECTRUM SPF 50
Water Resistant (80 Minutes)
Large spectre • Résiste à l'eau (80 minutes)

All Skin Types / Tous Types de Peau

75 ml (2.5 fl oz)

EPIONCE ULTRA SHIELD

homosalate, octisalate, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42673-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.101 g in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.1 g in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.05 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
LINSEED OIL (UNII: 84XB4DV00W)	
MALIC ACID (UNII: 817L1N4CKP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DATE (UNII: H3O7QI5HY7)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARETH-2 (UNII: V56DFE46J5)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	
TRIMETHYLSILOXYSILICATE (M/Q 0.66) (UNII: 5041RX63GN)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
STEARETH-21 (UNII: 53J3F32P58)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42673-011-02	1 in 1 BOX	04/06/2009	08/31/2024
1	NDC:42673-011-01	75 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:42673-011-05	1 in 1 BOX	04/06/2009	08/31/2024
2	NDC:42673-011-04	30 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:42673-011-00	6 g in 1 TUBE; Type 0: Not a Combination Product	04/06/2009	08/31/2024
4	NDC:42673-011-03	454 g in 1 JAR; Type 0: Not a Combination Product	04/06/2009	08/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/06/2009	08/31/2024

Labeler - Episciences, Inc. (144733040)

Establishment

Name	Address	ID/FEI	Business Operations
Episciences, Inc.		144733040	manufacture(42673-011)

Revised: 9/2022

Episciences, Inc.