ERYFOTONA ACTINICA ULTRALIGHT EMULSION- sunscreen emulsion
ISDIN Corp
Reference Label Set Id: 2c6423f1-43cb-15fb-e054-00144ff8d46c

Eryfotona Actinica® Ultralight Emulsion

Drug Facts

Active ingredient

Zinc Oxide 11%

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

Warning

- **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 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
- During sun exposure, reapply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- **Sun Protection Measures:** Spending time in the sun increases the risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with 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- sleeve shirts, pants, hats and sunglasses
- Children under 6 months: ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

Water, Diethylhexyl Carbonate, Dibutyl Adipate, Cyclopentasiloxane, Dicaprylyl Carbonate, Alcohol Denat., Cyclohexasiloxane, Butylene Glycol, PEG-30 Dipolyhydroxystearate, Nylon-12, PEG-10 Dimethicone, Dimethicone, Sodium Chloride, Phenoxyethanol, Disteardimonium Hectorite, Triethoxycaprylylsilane, Tocopheryl Acetate, Glyceryl Stearate, Fragrance, Bisabolol, Disodium EDTA, Ethylhexylglycerin, Panthenol, PEG-8, Tocopherol, Lecithin, Plankton Extract, Ascorbyl Palmitate, Ascorbic Acid, Citric Acid.

Questions or comments?

Call (862) 242-8129
Monday – Friday
(9 a.m. to 5 p.m. EST)
or visit www.isdin/us
USA Patent Pending

PRINCIPAL DISPLAY PANEL - 100 mL Bottle Carton

ISDIN
PHOTO

Eryfotona
Actinica®

Ultralight Emulsion

BROAD SPECTRUM SPF 50+

Designed for
Actinic Damage

Sunscreen with
DNA Repairsomes™
and antioxidants.

Water resistant
(40 minutes)

100% MINERAL
SUNSCREEN

3.4 FL OZ (100 mL)

ISDIN
PHOTO
Eryfotona Actinica®
Ultralight Emulsion

Drug Facts
(continued)

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(9 a.m. to 5 p.m. EST)
or visit www.isdin.com

This feel-good, lightweight formula is ideal for all skin types.

Eryfotona Actinica ® has been developed to help prevent actinic damage with 3 key ingredients:

Zinc Oxide: A 100% mineral sunscreen

DNA Repairsomes™: Contains Photolyase that has been shown to help repair sun damaged skin.

Antioxidants: To address photoaging caused by sun exposure

Dermatologist tested.

Broad spectrum sunscreens with a high SPF work to absorb or deflect the sun's UVA and UVB rays.

UVB rays, the primary cause of sunburn, affect the surface layers of the skin. UVA rays penetrate deeper into skin, damaging collagen and elastin, resulting in signs of premature aging.

Sun exposure causes progressive changes resulting in skin lesions that accumulate over the years: known as actinic damage. Areas with chronic sun

ISDIN
PHOTO

Eryfotona Actinica®

Ultralight Emulsion

BROAD SPECTRUM SPF 50+

Designed for
Actinic Damage

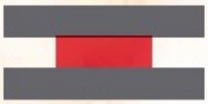
Sunscreen with
DNA Repairsomes™
and antioxidants.

Water resistant
(40 minutes)

exposure (face, forehead, ears, chest, scalp and back of hands) may develop actinic damage that shows up as wrinkles, discoloration, or flaky, itchy raised spots.

100% MINERAL SUNSCREEN

3.4 FL OZ (100 mL)



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SHAKE BEFORE USE

Drug Facts

Active ingredient	Purpose
Zinc Oxide 11%	Sunscreen

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Shake before use Apply generously

Eryfotona Actinica® 2019
Manufactured in Spain for ISDIN Corp.
Morristown NJ 07960
Phone (862) 242-8129
www.isdin.com
Ref. 690017690 NDC 69494-302-30

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EXP:MM/YYYY
LOT:OOOOO

ERYFOTONA ACTINICA ULTRALIGHT EMULSION

sunscreen emulsion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69494-302
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	11 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
WATER (UNII: 059QF0KO0R)	
DIETHYLHEXYL CARBONATE (UNII: YCD50O0Z6L)	
Dibutyl Adipate (UNII: F4K100DXP3)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
Dicaprylyl Carbonate (UNII: 609A3V1SUA)	
Alcohol (UNII: 3K9958V90M)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
Butylene Glycol (UNII: 3XUS85K0RA)	
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)	
Nylon-12 (UNII: 446U8J075B)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
Dimethicone (UNII: 92RU3N3Y1O)	
Sodium Chloride (UNII: 451W47IQ8X)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LEVOMENOL (UNII: 24WE03BX2T)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Panthenol (UNII: WV9CM0O67Z)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
Tocopherol (UNII: R0ZB2556P8)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	
Ascorbic Acid (UNII: PQ6CK8PD0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ANACYSTIS NIDULANS (UNII: UV4FTL6UAW)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69494-302-30	1 in 1 CARTON	11/01/2019	
1		100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:69494-302-10	1 in 1 CARTON	11/01/2019	01/01/2021
2		10 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:69494-302-12	1 in 1 CARTON	11/01/2019	
3		2 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:69494-302-13	1 in 1 CARTON	05/01/2023	
4		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:69494-302-14	12 in 1 CARTON	10/30/2023	
5		4 mL in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:69494-302-11	12 in 1 CARTON	12/18/2023	
6		2 mL 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 drug	M020	08/17/2015	

Labeler - ISDIN Corp (079609155)

Registrant - ISDIN Corp (079609155)

Revised: 12/2023 ISDIN Corp