

EEZY SUN SPF 30- meradimate, octinoxate, octocrylene, titanium dioxide, zinc oxide cream
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BIO EARTH MANUFACTURING (PTY) LTD

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.

Eezy Sun

Actives

Meradimate, Octinoxate, Octocrylene, Titanium Dioxide, Zinc Oxide

Inactives

Bulbine Fruitescence leaf oil, Cellulose gum, Cetearyl alcohol, Glycerin, Glycerol Stearate, Methylparaben, Phenoxyethanol, Propylparaben, Vit E, Vit A, Water, White petrolatum, Xanthan gum

Dosage and Administration

Directions

Apply liberally 15 minutes before sun exposure Reapply

PLEASE RECYCLE

DISTRIBUTED BY SANRIA26 (PTY) LTD 9428 ASHFORD PLACE BRENTWOOD, TN 37027
INFO@EEZYSUN.COM PRODUCT OF SOUTH AFRICA

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 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 Children under 6 months of age: Ask a docto

Warnings

For external use only

Do not use : On Damaged on broken skin.

Stop use and ask a doctor if rash occurs

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

Product Label SPF 30



Drug Facts

Active Ingredients	Purpose
Meradimate 3%, Octinoxate 7.5%, Octocrylene 4%, Titanium Oxide 5%, Zinc Oxide 9%	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
When using this product ■ keep out of eyes. Rinse with water to remove.
Stop use and ask a doctor if ■ rash occurs
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Drug Facts (continued)

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 ■ Children under 6 months of age: Ask a doctor

Other Information
 ■ Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients
 Bulbine frutescense leaf oil, cellulose gum, cetearyl alcohol, glycerin, glycerol stearate, methylparaben, phenoxyethanol, propylparaben, vitamin E, vitamin A, water, white petrolatum, xanthan gum.

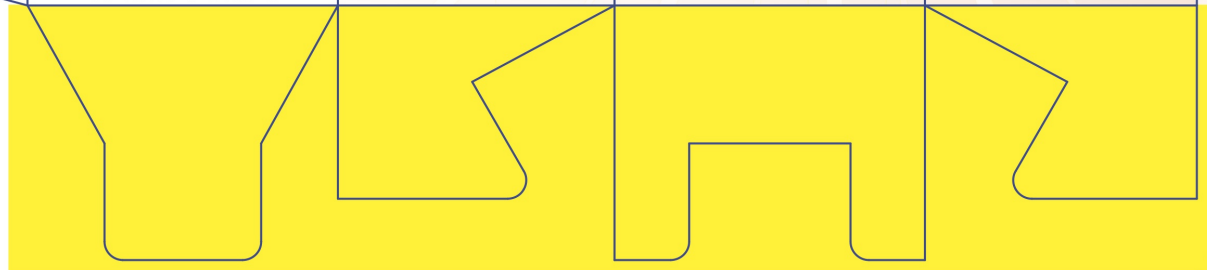


SUNSCREEN
BROAD SPECTRUM SPF 30
WATER RESISTANT
 (40 MINUTES)

10 packets, 0.27 fl oz (8 ml) each



HOW TO OPEN THE SNAP PACKET





BROAD SPECTRUM SPF 30
SUNSCREEN
WATER RESISTANT
(40 MINUTES)

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Drug Facts (continued)

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Other Information

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Inactive Ingredients

Bulbine frutescense leaf oil, cellulose gum, cetearyl alcohol, glycerin, glycerol stearate, methylparaben, phenoxethanol, propylparaben, vitamin E, vitamin A, water, white petrolatum, xanthan gum.



BE UV SMART EezySun

SUNSCREEN
BROAD SPECTRUM SPF 30
WATER RESISTANT
(40 MINUTES)

10 packets, 0.27 fl oz (8 ml) each

HOW TO OPEN THE SNAP PACKET





Product Label SPF 50



Drug Facts

Active Ingredients	Purpose
Meradimate 5%, Octinoxate 7.5%, Octocrylene 8%, Titanium Oxide 7%, Zinc Oxide 11 %	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
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Drug Facts (continued)

Directions

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Other Information

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Inactive Ingredients
Bulbine frutescense leaf oil, cellulose gum, cetearyl alcohol, glycerin, glycerol stearate, methylparaben, phenoxyethanol, propylparaben, vitamin E, vitamin A, water, white petrolatum, xanthan gum.

HOW TO OPEN THE SNAP PACKET

1. SNAP
2. BEND
3. PRESS

Drug Facts
Active Ingredients
 Meradimate 5%, Octinoxate 7.5%,
 Octocrylene 8%, Titanium Oxide 7%,
 Zinc Oxide 11 %
 Purpose: Sunscreen

Uses
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Drug Facts (continued)
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SPF 50
EEzySun
 BE UV SMART
 SUNSCREEN
BROAD SPECTRUM SPF 50
WATER RESISTANT
 (40 MINUTES)
 10 packets, 0.27 fl oz (8 ml) each

HOW TO OPEN THE SNAP PACKET
 1. SNAP
 2. BEND
 3. PRESS

EEZY SUN SPF 30

meradimate, octinoxate, octocrylene, titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 116-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MERADIMATE (UNII: J9QGD60OUZ) (MERADIMATE - UNII:J9QGD60OUZ)	MERADIMATE	30 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	40 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	50 mg in 1 mL

Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	90 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
BULBINE FRUTESCENS WHOLE (UNII: M2U1C7UW6Y)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
VITAMIN A (UNII: 81G40H8B0T)	
WATER (UNII: 059QF0K00R)	
PETROLATUM (UNII: 4T6H12BN9U)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70116-001-01	8 mL in 1 POUCH; Type 0: Not a Combination Product	12/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/14/2017	

EEZY SUN SPF 50

meradimate, octinoxate, octocrylene, titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70116-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MERADIMATE (UNII: J9QGD60OUZ) (MERADIMATE - UNII:J9QGD60OUZ)	MERADIMATE	50 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	80 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	70 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	110 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BULBINE FRUTESCENS WHOLE (UNII: M2U1C7UW6Y)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
VITAMIN A (UNII: 81G40H8B0T)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70116-002-01	8 mL in 1 POUCH; Type 0: Not a Combination Product	12/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/14/2017	

Labeler - BIO EARTH MANUFACTURING (PTY) LTD (639768436)

Establishment

Name	Address	ID/FEI	Business Operations
BIO EARTH MANUFACTURING (PTY) LTD		639768436	manufacture(70116-001, 70116-002)

Revised: 12/2017

BIO EARTH MANUFACTURING (PTY) LTD