

CONCEALER BROAD SPECTRUM SUNSCREEN SPF 30- titanium dioxide, zinc oxide cream
Epione Medical Corporation

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.

Concealer Broad Spectrum SPF 30

Active Ingredients :

Titanium Dioxide 5.00%

Zinc Oxide 10.00%

Uses :

Helps prevent sunburn

If used as direct with other sun protection measures (see □ **Directions**□), decreases the risk of skin cancer and early aging caused by the sun.

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

Stop use/ contact a doctor if rash occurs

Warnings:

For external use only

Do not use on damaged or broken skin

Avoid contact with eyes. Rinse with water to remove

Directions :

Apply evenly 15 minutes before sun exposure

Reapply at least every 2 hours

Use a water resistant sunscreen if swimming or sweating

Children Under 6 months: Ask a doctor.

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 a broad spectrum SPF of 15 or higher and other sun protection measures including:

limit time in the sun, especially from 10a.m.-2p.m.

Wear long-sleeved shirt, pants, hats, and sunglasses

Reapply at least every 2 hours

Water, Coconut Alkanes, Octyldodecyl Neopentanoate, Butylene Glycol, C12-15 Alkyl Benzoate, Polysorbate 60, Cyclopentasiloxane, Dimethicone, Cetearyl Alcohol, Glycerine, Polysorbate 60, Polyacrylamide, Polyhydroxystearic Acid, Glyceryl Stearate, PEG-100 Stearate, Phenoxyethanol, C13-14 Isoparaffin, Coco-Caprylate/Caprates, Stearic Acid, Acrylates/C10-30 Alkyl Acrylates Crosspolymer, Ethylhexylglycerin, Alumina, Xanthan Gum, Laureth-7, Triethanolamine, Iron Oxides(CI 77499, CI 77491, CI77492).

Epione

Concealer Broad Spectrum SPF 30+

1.0 FL OZ (30mL)

1.000 in



E P I O N E
B E V E R L Y H I L L S

CONCEALER
BROAD SPECTRUM
SPF 30+

AM

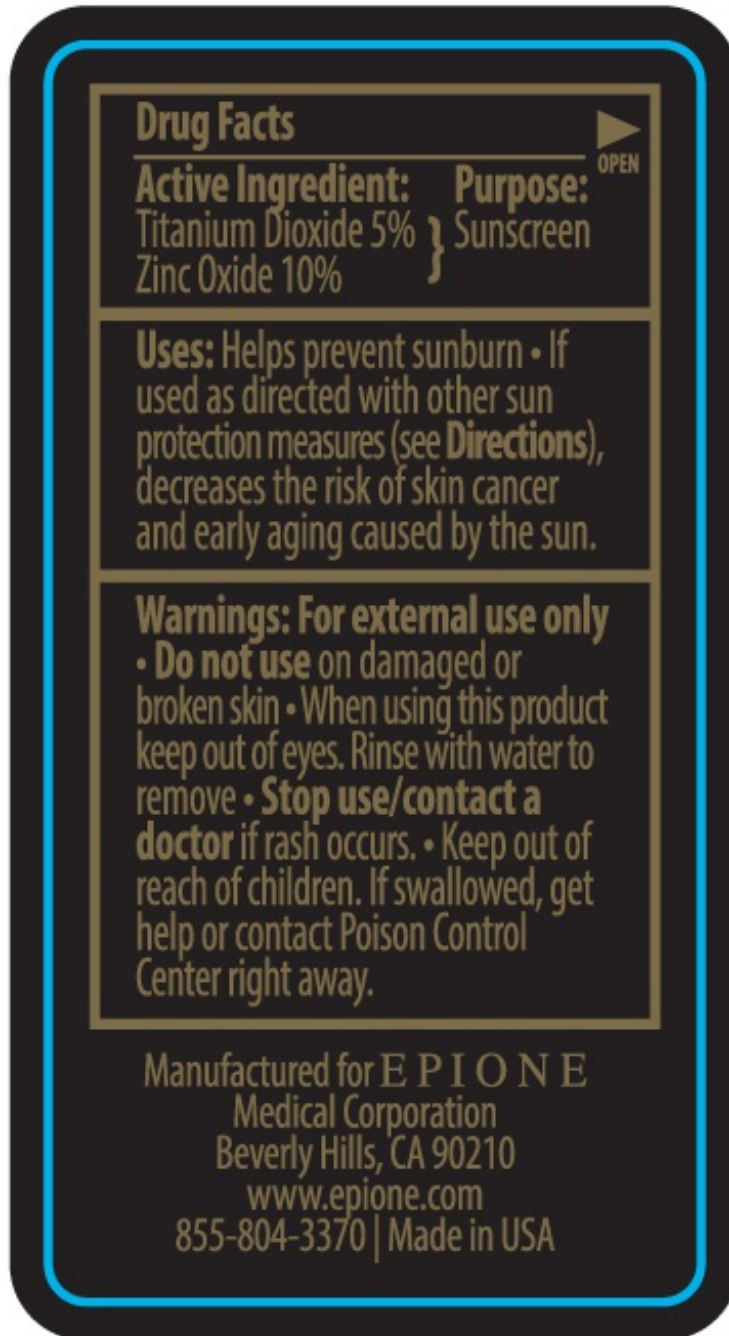
1.0 FL OZ (30 mL)

2.000 in



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Drug Facts cont.

Directions: Apply liberally evenly 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating • Children Under 6 months: Ask a doctor.

Sun Protection Measures:

Spending time in the sun increases your risk of cancer and early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF value of 15 or higher • Other sun protection measures include: limiting time under the sun, especially from 10am–2pm • Wear long-sleeved shirts, pants, hats, and sunglasses.

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NOTE: Art adjusted to fit within text limit

Drug Facts cont.

Inactive Ingredients:

Water, Coconut Alkanes, Octyldodecyl Neopentanoate, Butylene Glycol, C12-15 Alkyl Benzoate, Polysorbate 60, Cyclopentasiloxane, Dimethicone, Cetearyl Alcohol, Glycerine, polysorbate 60, Polyacrylamide, Polyhydroxystearic Acid, Glyceryl Stearate, PEG-100 Stearate, Phenoxyethanol, C13-14 Isoparaffin, Coco-Caprylate/Caprate, Stearic Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Ethylhexylglycerin, Alumina, Xanthan Gum, Laureth-7, Triethanolamine, Iron Oxide (CI 77499, CI 77491, CI 77492).

Manufactured for E P I O N E
Medical Corporation
Beverly Hills, CA 90210
www.epione.com
855-804-3370 | Made in USA

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CONCEALER BROAD SPECTRUM SUNSCREEN SPF 30

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70698-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
LAURETH-7 (UNII: Z95S6G8201)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70698-004-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/05/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/05/2018	

Labeler - Epione Medical Corporation (088809509)

Establishment

Name	Address	ID/FEI	Business Operations
VEGE-KURL, INC		021072509	manufacture(70698-004)

Revised: 7/2018

Epione Medical Corporation