

CAMOUFLAGE CONCEALER CREAM- octinoxate cream

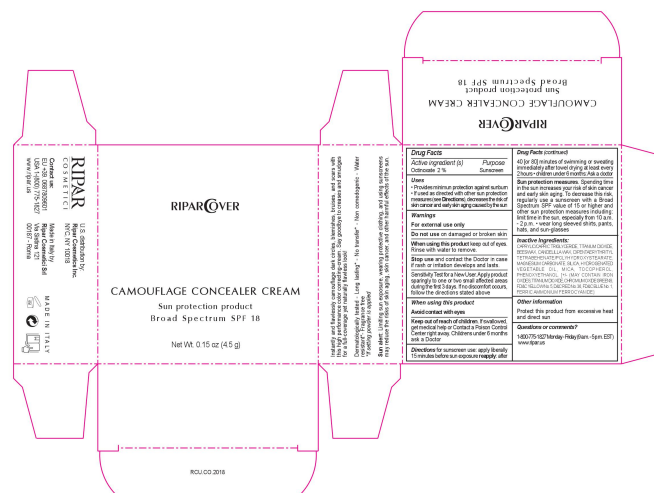
Ripar Cosmetici srl

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.

Camouflage Concealer Cream

ACTIVE INGREDIENTS PURPOSE

Oxtinoxate 2% sunscreen



Warnings

SUN ALERT: Limiting sun exposures, wearing protective clothing and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun

For external use only.

Do not use on damaged or broken skin.

When using this product keep our of the eyes. Rinse with water to remove.

SUN PROTECTION MEASURES. Spending times 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 15 or higher and other sun protection measures including: limit time to the sun especially from 10:00 am to 2:00 pm. Wear long sleeve shirts, pants, hats and sunglasses

Discontinue use if signs or irritation or rash appears. If irritation or rash persists, consult with a doctor.

Keep out of reach of children. If swallowed, get medical help or Contact Poison Control Central right away

Children under 6 months ask a doctor

WARNINGS

Children under 6 months: ask a doctor

Warnings

Keep out of reach of children

Questions or comments?

1- 800-775-1827. M-F 9:00 am to 5:00 pm EST

www.ripar.us

Other Information

Protect this product from excessive heat and direct sun

Directions

- provides minimum protection against sunburn
- if used as directed with other sun protection measures (see directions), decreases the risks of skin cancer and early skin aging caused by the sun
- apply liberally 15 minutes before sun exposure reapply after 40 or 80 minutes of swimming or sweating immediately after towel drying at least every 2 hours
- children under 6 months of age, consult with a doctor

Uses

- provides minimum protection against sunburn
- if used as directed with other sun protection measures (see directions), decreases the risks of skin cancer and early skin aging caused by the sun

Inactive Ingredients

CAPRYLIC/CAPRIC TRIGLYCERIDE, MEDIUM CHAIN TRIGLYCERIDES, BEESWAX YELLOW WAX, CANDELILLA WAX, OCTINOXATE, DIPENTAERYTHRITYL TRIPOLYHYDROXYSTEARATE, MAGNESIUM CARBONATE, SILICON DIOXIDE, HYDROGENATED PALM, MICA, TOCOPHEROL, PHENOXYETHANOL, FERRIC OXIDE YELLOW, FERRIC OXIDE RED, TITANIUM DIOXIDE, FD&C YELLOW No.5, D&C RED No. 36

Uses

- provides minimum protection against sunburn
- if used as directed with other sun protection measures (see directions), decreases the risks of skin

cancer and early skin aging caused by the sun

Package Label



CAMOUFLAGE CONCEALER CREAM

octinoxate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72399-107
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	2 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			

YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328HX19)	
DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE (UNII: D21K655H52)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROGENATED PALM OIL (UNII: 257THB963H)	
MICA (UNII: V8A1AW0880)	
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 36 (UNII: OE8ZA0KN9Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72399-107-02	1 in 1 BOX	06/19/2018	
1	NDC:72399-107-01	4 mL in 1 CYLINDER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/19/2018	

Labeler - Ripar Cosmetici srl (338675564)

Registrant - Ripar Cosmetici srl (338675564)

Establishment

Name	Address	ID/FEI	Business Operations
338675564		338675564	manufacture(72399-107)