EXTRALASTING CREAM-TO-POWDER FOUNDATION- octinoxate, titanium dioxide cream New Avon LLC

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.

Active ingredients

Octinoxate 6.34%.....

Titanium Dioxide 3.00%......

Purpose
......Sunscreen

Uses

• helps prevent sunburn

.....Sunscreen

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

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

Directions

- apply liberally 15 minutes before sun exposure
- children under 6 months of age: ask a doctor
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- 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 the product in this container from excessive heat and direct sun

Inactive ingredients: Propylene Glycol Dicaprylate/Dicaprate, Diisopropyl Dimer Dilinoleate, Microcrystalline Wax/Cire Microcristalline, Nylon-12, Cetyl Ricinoleate, Hydrogenated Coco-Glycerides, Silica, Tribehenin, Punica Granatum Sterols, Polymethyl Methacrylate, Ethylene/Methacrylate Copolymer, Propylparaben, VP/Hexadecene Copolymer, Dimethicone, Ethylparaben, Triethoxycaprylylsilane, Glyceryl Rosinate, Octyldodecyl Myristate, Magnesium Myristate, Butylparaben, Tocopheryl Acetate, Isopropyl Titanium Triisostearate. May Contain: Titanium Dioxide/CI 77891, Iron Oxides, Mica/CI 77019, Bismuth Oxychloride/CI 77163.

Questions or Comments? Call toll free 1-800-FOR-AVON or 1-800-265-AVON in Canada



Drug Facts (continued)

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Drug Facts Active ingredients Purpose Octinoxate 6.34% Sunscreen Titanium Dioxide 3.00% helps prevent sunburn For external use only Do not use on damaged or broken skin **hen using this product** keep out of eyes. Rinse with water to remove.

EXTRALASTING CREAM-TO-POWDER FOUNDATION

octinoxate, titanium dioxide cream

Product Information

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:10096-0231

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	63.4 mg in 1 g
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	30 mg in 1 g

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:10096-0231-2	1 in 1 CARTON			
1	NDC:10096-0231-1	9 g in 1 CASE; 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	12/15/2010				

Labeler - New Avon LLC (080143520)

Establishment				
Name	Address	ID/FEI	Business Operations	
Avon Products, Inc.		544863277	manufacture(10096-0231)	

Revised: 2/2016 New Avon LLC