ANEW PLATINUM DAY- octinoxate, octisalate, oxybenzone, avobenzone 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.

Anew Platinum Day Cream

Active ingredients

OCTINOXATE 7.5%, OCTISALATE 4.75%, OXYBENZONE 4.0%, AVOBENZONE 2.85%.....

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

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: WATER, GLYCERIN, SILICA, DIMETHICONE, STEARIC ACID, STEARYL ALCOHOL, NONENOL, SAPINDUS RARAK FRUIT EXTRACT, POUZOLZIA PENTANDRA EXTRACT, METHOXYBENZOYL METHYLSULFONYL OXOPIPERIDINYL PIPERAZINECARBOXAMIDE, THIAZOLYLALANINE, SACCHAROMYCES/PLATINUM FERMENT, TRISILOXANE, DIMETHICONOL, MYRISTYL MYRISTATE, MALTODEXTRIN, PEG-100 STEARATE, CAPRYLYL GLYCOL, GLYCERYL STEARATE, SODIUM POLYACRYLATE, POLYURETHANE-40, POTASSIUM HYDROXIDE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, DISODIUM EDTA, 1,2-HEXANEDIOL, PARFUM.

Questions? 1-800-FOR-AVON



Drug Facts

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Drug Facts (continued)

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- 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: Water, Glycerin, Silica, Dimethicone, Stearic Acid, STEARYL ALCOHOL, NONENOL, SAPINDUS RARAK FRUIT EXTRACT, POUZOLZIA PENTANDRA EXTRACT, METHOXYBENZOYL METHYLSULFONYL OXOPIPERIDINYL PIPERAZINECARBOXAMIDE, THIAZOLYLALANINE, SACCHAROMYCES/PLATINUM FERMENT, TRISILOXANE, DIMETHICONOL, MYRISTYL MYRISTATE, MALTODEXTRIN, PEG-100 STEARATE, CAPRYLYL GLYCOL,GLYCERYL STEARATE, SOOIUM POLYACRYLATE, POLYURETHANE-40, POTASSIUM HYDROXIDE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, DISODIUM EDTA, 1,2-HEXANEDIOL, PARFUM.

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ANEW PLATINUM DAY

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10096-0224
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
O CTINO XATE (UNII: 4Y5P7MUD51) (OCTINO XATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	47.5 mg in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28.5 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10096-0224-2	1 in 1 CARTON	09/07/2019	
1	NDC:10096-0224-1	50 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:10096-0224-4	1 in 1 CARTON	09/07/2010	
2	NDC:10096-0224-3	15 g in 1 JAR; Type 0: Not a Combination Product		
3	NDC:10096-0224-6	1 in 1 CARTON	09/07/2010	
3	NDC:10096-0224-5	7 g in 1 JAR; Type 0: Not a Combination Product		
4	NDC:10096-0224-7	1.1 g in 1 PACKET; Type 0: Not a Combination Product	09/07/2010	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	09/07/2010		

Labeler - New Avon LLC (080143520)

Establishment				
Name	Address	ID/FEI	Business Operations	
Fareva Morton Grove, Inc.		116752326	manufacture(10096-0224)	

Revised: 1/2019 New Avon LLC