NU-DERM HEALTHY SKIN PROTECTION SPF 35- octinoxate and zinc oxide cream
OBAGI COSMECEUTICAL 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.

NU-DERM
HEALTHY SKIN
PROTECTION
SPF 35

Drug Facts

Active ingredients	***Purpose***
Octinoxate 7.5%	Sunscreen
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

Stop use and ask a doctor if rash occurs

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

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
- use a water resistant sunscreen if swimming or sweating
- reapply 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: Ask a doctor

Other information

- store at controlled room temperature: 15°-25°C (59°-77°F)
- protect this product from excessive heat and direct sun

Inactive ingredients

butylparaben, cetearyl alcohol, citric acid, C13-14 isoparaffin, DEA-cetyl phosphate, disodium EDTA,

ethylhexyl stearate, ethylparaben, isobutylparaben, isopropyl palmitate, laureth-7, methylparaben, phenoxyethanol, polyacrylamide, polyether-1, polysorbate 60, propylparaben, sodium hydroxide, triethoxycaprylylsilane, water (aqua)

Questions or comments?

1.800.636.7546 Monday−Friday 9 a.m.−4p.m. Pacific Time

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - 85 g Bottle Label

RECOMMENDED
SKIN
CANCER
FOUNDATION
DAILY USE

The Skin Cancer Foundation
recommends this Product as an
effective UVA/UVB sunscreen

OBAGI
NU-DERM®

AM
HEALTHY SKIN
PROTECTION

BROAD SPECTRUM SPF 35

6
SUNSCREEN LOTION

Net wt. 3 oz. (85 g)

NU-DERM HEALTHY SKIN PROTECTION SPF 35

octinoxate and zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62032-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	90 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
LAURETH-7 (UNII: Z95S6G8201)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62032-200-90	90 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2002	03/31/2020
2	NDC:62032-200-01	1 in 1 CARTON	04/01/2020	
2		85 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part352	01/01/2002	

Labeler - OBAGI COSMECEUTICAL LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(62032-200)

Revised: 9/2019 OBAGI COSMECEUTICAL LLC