NU-DERM SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN- octinoxate and zinc oxide lotion
OMP, Inc.

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® SUN SHIELD BROAD SPECTRUM SPF 50
MATTE SUNSCREEN LOTION

Active ingredients

Octinoxate 7.5%, Zinc Oxide 10.5%

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. Children under 6 months: Ask a doctor.

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.

Inactive ingredients

1,2-hexanediol, caprylyl glycol, ceteareth-20, cetearyl alcohol, chlorphenesin, citric acid, cyclopentasiloxane, dimethicone crosspolymer-3, disodium EDTA, hydrogenated palm glycerides, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, methylisothiazolinone, PEG-10 dimethicone, PEG-40 stearate, pentylene glycol, phenyl trimethicone, polysilicone-11, polysorbate 60, potassium sorbate, sodium benzoate, sodium dihydroxycetyl phosphate, squalane, stearyl alcohol, tetrahexyldecyl ascorbate, tocopheryl acetate, tropolone, ubiquinone, water, xanthan gum

Other information

Store at controlled room temperature: 15°C–25°C (59°F–77°F). Protect this product from excessive heat and direct sun.

Questions or comments?

1.800.636.7546

Monday–Friday 9 a.m.–4 p.m. Pacific Time

Distributed by OMP, Inc., Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - 85 g Tube Label

OBAGI
NU-DERM®

Sun Shield

MATTE

Broad
Spectrum
SPF 50

Sunscreen
Lotion
PA+++

Net wt. 3 oz. (85 g.)

NU-DERM SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

octinoxate and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62032-104
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 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	105 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
WATER (UNII: 059QF0KO0R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
SODIUM DIHYDROXYCETYL PHOSPHATE (UNII: YWI33EV595)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TROPOLONE (UNII: 7L6DL16P1T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
UBIDECARENONE (UNII: EJ27X76M46)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-104-90	85 g in 1 TUBE		
2	NDC:62032-104-10	28 g in 1 TUBE		

Marketing Information

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

OTC MONOGRAPH FINAL	part352	11/07/2012	

Labeler - OMP, Inc. (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
MILBAR LABORATORIES		195556790	MANUFACTURE(62032-104)

Revised: 12/2012 OMP, Inc.