SUNSCREEN BROAD SPECTRUM SPF 55 MOISTURIZING- octinoxate and zinc oxide cream Scars dale Integrative Family Medicine Pllc

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.

Sunscreen Broad Spectrum SPF 55 Moisturizing Lotion DRUG FACTS

ACTIVE INGREDIENTS

Octinoxate 7.5%

Zinc Oxide 4.8%

PURPOSE

Sunscreen

USES

Help prevent sunburn.

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 or irritation occurs.

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

DIRECTIONS

Apply liberally and evenly 15 minutes before sun exposure. ¹Reapply:

At least 80 minutes after swimming or sweating, immediately after towel drying, 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 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-sleeve shirts, pants, hats, and sunglasses.

INACTIVE INGREDIENTS

Water, Hydrogenated Polybutene, Octyl Stearate, Polyglyceryl-4-Isostearate, Aloe Barbadensis Leaf Extract, Isopropyl Palmitate, Cyclomethicone, Sunflower Oil, Hydrogenated Microcrystalline Wax, Cetyl Dimethicone Copolyol, Cetyl Dimethicone, Hydrogenated Castor Oil, Sodium Chloride,

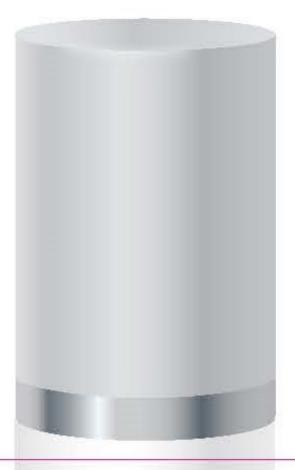
 $^{1\,}$ For children under 6 months of age: Ask a doctor.

Polyglyceryl-3-Oleate, Silica, Hexyl Laurate, Triethoxycaprylylsilane, Capryly Glycol, Methylisothiazolinone.

OTHER INFORMATION

Store at controlled temperature 15C - 30C (59F-86F). Protect the product in this container from excessive heat and direct sun.

See Beyond







*the above image is a digital representatiSee Beyond

Scarsdale Aesthetic Medicine Dynamic Broad Spectrum Snscreen SPF 55 Sun Protection

1.75 fl Oz (50ml)

SUNSCREEN BROAD SPECTRUM SPF 55 MOISTURIZING

octinoxate and zinc oxide cream

Active Ingredient/Active Moiety

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81413-5550	
Route of Administration	TOPICAL			

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	48 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
SORBITOL (UNII: 506T60A25R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALCOHOL (UNII: 3K9958V90M)	
OCTISALATE (UNII: 4X49 Y0596 W)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
VINYLPYRROLIDONE/EICO SENE COPOLYMER (UNII: 035MV9S1C3)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: $86 \text{FQE} 96 \text{TZ} 4$)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
BETULA PUBESCENS BARK (UNII: 3R504894L9)	
GARDEN CRESS SPROUT (UNII: PWQ18 YNR62)	
SAGE (UNII: 065C5D077J)	
COLA ACUMINATA SEED (UNII: 1F8 VIW1479)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ISOMALT (UNII: S870P55O2W)	
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81413-5550- 2	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/22/20 21	

Marketing Inform	Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part352	01/22/2021			

Labeler - Scarsdale Integrative Family Medicine Pllc (004329015)

Revised: 1/2021

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