

**RETEXTURIZING PRIMER BROAD SPECTRUM SPF 20- retexturizing primer
broad spectrum spf 20 cream
MANA PRODUCTS,INC.**

RETEXTURIZING PRIMER BROAD SPECTRUM SPF 20

ACTIVE INGREDIENTS

Avobenzone 2%

Octinoxate 7.5%

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

DIRECTIONS

- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water-resistant sunscreen if swimming or sweating.
- Sun Protection Measures:
- Spending time in the sun increases risk of skin cancer and early 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 10:00 a.m. - 2:00 p.m.

- wear long sleeved shirts, pants, hats and sunglasses.
- Children under 6 months of age: ask a doctor.

OTHER INFORMATION

Protect the product in this container from excessive heat and direct sun.

INACTIVE INGREDIENTS

Cyclopentasiloxane, Dimethicone Crosspolymer, Polysilicone-11, C12-15 Alkyl Benzoate,

Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Laureth-12, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Retinyl Palmitate, Salicylic Acid, Mica, Silica, Phenoxyethanol, Titanium Dioxide

Stop use and ask a doctor if rash occurs.

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

PACKAGE LABELS.PRINCIPLE DISPLAY PANEL



RETEXTURIZING PRIMER BROAD SPECTRUM SPF 20

retexturizing primer broad spectrum spf 20 cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g

OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
LAURETH-12 (UNII: OAH19558U1)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-800-02	1 in 1 BOX	01/01/2017	
1	NDC:59735-800-01	28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:59735-800-04	1 in 1 BOX	01/01/2017	
2	NDC:59735-800-03	28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:59735-800-06	1 in 1 BOX	01/01/2017	
3	NDC:59735-800-05	28 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:59735-800-08	1 in 1 BOX	01/01/2017	
4	NDC:59735-800-07	28 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/01/2017	

Labeler - MANA PRODUCTS,INC. (078870292)

Establishment

Name	Address	ID/FEI	Business Operations
MANA PRODUCTS, INC		032870270	manufacture(59735-800)

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MANA PRODUCTS,INC.		078870292	manufacture(59735-800)

Revised: 8/2024

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