PRIVATE LABEL SUNSCREEN SPF35 40MIN WR RE126-202- homosalate, zinc oxide sunscreen lotion
Swiss-American CDMO, LLC

Private Label Sunscreen SPF35 40min WR RE126-202

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 physician if rash occurs. If product is swallowed get medical help or contact a Poison Control Center right away.

Active Ingredients

Homosalate 9.0% Sunscreen
Zinc Oxide 10.0% Sunscreen
Octisalate 5.0% Sunscreen

uses

Helps prevent sunburn. If used as directed with other sun protection measure (See Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

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Directions

Apply liberally 15 minutes before sun exposure. Reapply after 40 minutes of swimming or sweating, immediately after towel drying and 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 am to 2 pm. Wear long-sleeve shirts, pants, hats, and sunglasses. Children under 6 months: ask a physician.

Keep out of reach of children

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Other information:

Protect this product from excessive heat and direct sun.

Inactive Ingredients

Water, dimethicone, PEG-10 dimethicone, euphorbia cerifera (Candelilla) Wax, Caprylic/Capric Trigylceride, sodium chloride, phenoxyethanol, polyhydroxystearic acid, triethoxycaprylylsilane, saccharide isomerate, ethylhexylglycerin, dl-alpha tocopheryl acetate, glycerin, disodium EDTA, xanthan gum, Gossypium herbaceum (Cotton) extract, citric acid, sodium citrate, benzyl alcohol, gluconolactone, sodium benzoate, calcium gluconate

Questions?

Call toll free 1-866-416-2366

Labeling

PRIVATE LABEL SUNSCREEN SPF35 40MIN WR RE126-202

homosalate, zinc oxide sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60232-0036
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	90 g in 1000 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	100 g in 1000 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CANDELILLA WAX (UNII: WL0328HX19)	
PEG-10 DIMETHICONE (220 CST) (UNII: 287GF3Y3WC)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
GLYCERIN (UNII: PDC6A3C0OX)	
GOSSYPIUM HIRSUTUM WHOLE (UNII: 0Z88765ZGC)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60232-0036-1	30 g in 1 PACKAGE; Type 0: Not a Combination Product	11/09/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/09/2023	

Labeler - Swiss-American CDMO, LLC (080170933)

Registrant - Swiss-American CDMO, LLC (080170933)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(60232-0036)

Revised: 11/2023 Swiss-American CDMO, LLC