SOLBAR AVO SPF35- solbar avo spf35 cream
Person and Covey

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.

Solbar Avo SPF35

Indications and use

Helps prevent sunburn. If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun. Dosage and Administration: Apply liberally and evenly to all sun exposed areas of DRY skin 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating and immediately after towel drying. Apply at least every 2 hours. For children under 6 months, ask a physician.

Purpose

Sunscreen

Keep out of the reach of children

Yes. If swallowed, get medical help or contact a Poison Control Center right away.

Dosage and Administration

Apply liberally and evenly to all sun exposed areas of DRY skin 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating and immediately after towel drying. Apply at least every 2 hours. For children under 6 months, ask a physician.

Warnings

For external use only. Do not use on damaged or broken skin. Keep out of eyes. Rinse eyes thoroughly with water to remove. Stop use and ask a physician if rash or irritation develops and lasts. Store away from excessive heat and direct sun.

OTC - ACTIVE INGREDIENT SECTION

Homosalate

Octinoxate

Oxybenzone

Avobenzone

INACTIVE INGREDIENT SECTION

Water

Isobutyl Stearate

Glycerin

Benzyl Alcohol

Simethicone

Cetyl Phosphate

Triethanolamine

Stearic Acid

Silica

Carbomer 1342

Acrylates/C10-30 Alkyl Acrylate Crosspolymer

Disodium EDTA

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

solbar avo.jpg

SOLBAR AVO SPF35

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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0096-0687
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.08 g in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.06 g in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

ISOBUTYL STEARATE (UNII: V8DPR6HNX3)	
GLYCERIN (UNII: PDC6A3C0OX)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
TROLAMINE (UNII: 9O3K93S3TK)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOMER 1342 (UNII: 809Y72KV36)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0096-0687-04	119 g in 1 BOTTLE; Type 0: Not a Combination Product	06/01/1996	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/01/1996	

Labeler - Person and Covey (008482473)

Establishment

Name	Address	ID/FEI	Business Operations
Person and Covey		008482473	manufacture(0096-0687)

Revised: 10/2022 Person and Covey