MEIJER - avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion Meijer Distribution 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.

Drug Facts

Active Ingredients

Avobenzone 3.0% Homosalate 13.0% Octisalate 5.0% Octocrylene 7.0% Oxybenzone 4.0%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see *Directions*), decrease 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. May stain some fabrics.

When using this product

Keep out of eyes. Rinse with water to remove.

stop use and ask a doctor

if rash occurs

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
- reapply
- after 80 minutes of 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
- children under 6 months of age: Ask a doctor

Inactive Ingredients

Water, Sorbitol, Stearic Acid, Triethanolamine, Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Sorbitan Isostearate, VP/Eicosene Copolymer, Dimethicone, Polyglyceryl-3 Distearate, Carbomer, Tocopherol, Disodium EDTA, Methylparaben, Propylparaben, Fragrance.

Other Information

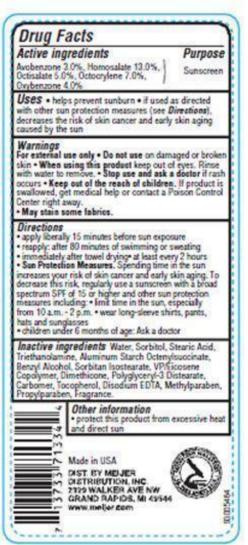
Protect this product from excessive heat and direct sun.

Principle Display Panel









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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-006	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 mL in 100 mL	

OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 mL in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 mL in 100 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	4 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TROLAMINE (UNII: 9O3K93S3TK)		
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ0 O 6 294)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
TOCOPHEROL (UNII: R0ZB2556P8)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
METHYLPARABEN (UNII: A2I8 C7HI9 T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		

Pa	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-006-57	295 mL in 1 BOTTLE		
2	NDC:41250-006-22	88 mL in 1 TUBE		
3	NDC:41250-006-19	473 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/0 1/20 12	

Labeler - Meijer Distribution Inc (006959555)

Revised: 1/2012 Meijer Distribution Inc