BROAD SPECTRUM SPF 30 PREFERRED PLUS PHARMACY- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion Kinray 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 2.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 4.0%, Oxybenzone 5.0%

Uses

Helps 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 occurs.

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 again. 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, specially from 10am - 2pm, wear long-sleeve shirts, pants, hats, and sunglasses.

Children under 6 months: ask a doctor.

Inactive ingredients

Acrylates/C10-30 Alykl Acrylate Crosspolymer, Benzyl Alcohol, Chlorphenesin, Disodium EDTA, Fragrance, Neopentyl Glycol Diheptanoate, Oleth-3, Polyamide-8, Propylene Glycol, Tocopherol, Triethanolamine, Water.

Purpose

Sunscreen.

Keep out of reach of children.

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

Preferred Plus Pharmacy

Broad Spectrum SPF 30

Water Resistant (80 Minutes)



BROAD SPECTRUM SE avobenzone, homosalate, octisal			MACY		
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:61715-024	
Route of Administration	TOPICAL				
Active Ingredient/Active Mo	iety				
Ingredient Name		Basis of Strength		Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)			AVOBENZONE		2 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)			HOMOSALATE		10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)			OCTISALATE		5 g in 100 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)) OCTOCRY	YLENE	4 g in $100 mL$	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)			OXYBENZ	CONE	5 in 100 mL	
Inactive Ingredients						
Ingredient Name						
CARBOMER 1342 (UNII: 8	809Y72KV36)					
BENZYL ALCOHOL (UNI	I: LKG8494WBH)					
EDETATE DISODIUM (UN	III: 7FLD91C86K)					
NEOPENTYL GLYCOL D	IHEPTANO ATE (UNII: 5LKW3C543X)					
OLETH-3 (UNII: BQZ2623	5UC)					
PROPYLENE GLYCOL (U	JNII: 6 DC9 Q 16 7 V3)					
TOCOPHEROL (UNII: R02	ZB2556P8)					
TRIETHANO LAMINE BEN	NZOATE (UNII: M3EN4GC19W)					
WATER (UNII: 059QF0KO	0 R)					
Packaging						
# Item Code	Package Description	Marketing Start Date		Marketing End Date		
1 NDC:61715-024-08	237 mL in 1 BOTTLE, PLASTIC					
Marketing Infor	mation					
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date	
OTC monograph not final	part352		0 3/15/20 13			
OIG monograph not imar			0 0/ 10/ 20 10			

Labeler - Kinray Inc. (012574513)

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Kinray Inc.