BROAD SPECTRUM SPF 50 KIDS 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 3.0%, Homosalate 13.0%, Octisalate 5.0%, Octocrylene 7.0%, Oxybenzone 4.0%

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

Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Fragrance, Methylparaben, Polyglceryl-3 Distearate, Propylparaben, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, 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 50

Kids Moisturizing Sunscreen Lotion

Water Resistant (80 Minutes)



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.Sunscreen Oxybenzone 4.0%.....

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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.

- 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: Ask a doctor

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

Other information

· protect this product from excessive heat and direct sun

ALL PREFERRED PLUS PHARMACY PRODUCTS ARE SATISFACTION GUARANTEED OR YOUR MONEY BACK FROM RETAILER WHERE PURCHASED.

Distributed by: KINRAY INC. 152-35 Tenth Avenue Whitestone, NY 11357

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BROAD SPECTRUM SPF 50 KIDS PREFERRED PLUS PHARMACY

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61715-028

Route of Administration **TOPICAL**

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 mL
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	4 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
ALUMINUM STARCH O CTENYLSUCCINATE (UNII: 19 PJ 0 O 6 29 4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470 XV)	
PROPYLPARABEN (UNII: Z8 IX2SC1OH)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0 ZB2556 P8)	
TRIETHANO LAMINE BENZO ATE (UNII: M3EN4GC19W)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:61715-028-08	237 mL in 1 BOTTLE, PLASTIC		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part352	03/15/2013			

Labeler - Kinray Inc. (012574513)

Revised: 5/2013 Kinray Inc.