

EXTRASHADE DAILY DEFENSE HYDRATING SUNSCREEN SPF 30- avobenzone, octinoxate, octisalate, oxybenzone lotion

Extrashade a Sub of Versatile Group

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.

EXTRASHADE Daily Defense Hydrating Sunscreen SPF 30

Active ingredients

Active ingredients	Purpose
Avobenzone 3.0%	
Octinoxate 7.5% Sunscreen	} Sunscreen
Octisalate 5.0%	
Oxybenzone 4.0%	

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases 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

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

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.

Inactive ingredients

Water (Aqua), Glyceryl Stearate, Ethylhexyl Methoxycrylene, Glycerin, Jojoba Esters, Dimethicone, VP/Eicosene Copolymer, Cetearyl Alcohol, Cetyl Dimethicone, Potassium Cetyl Phosphate, PEG-100 Stearate, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Tocopheryl Acetate, Tetrahexyldecyl Ascorbate, Sodium Hyaluronate, Hydroxyethylcellulose, Hexylene Glycol, Punica Granatum Quillaja (Pomegranate) Extract, Cocos Nucifera (Coconut) Extract, Hedychium Coronarium Root (White Ginger) Extract, Actinidia Chinensis (Kiwi Fruit) Extract, Hibiscus Rosa Sinensis Extract, Passion Flora Incarnata (Passion Flower) Extract, Plantago Major Leaf (Plantain) Extract, Saponaria Bark (Soap Bark) Extract

Other information

- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-888-637-5724

Purpose

Sunscreen

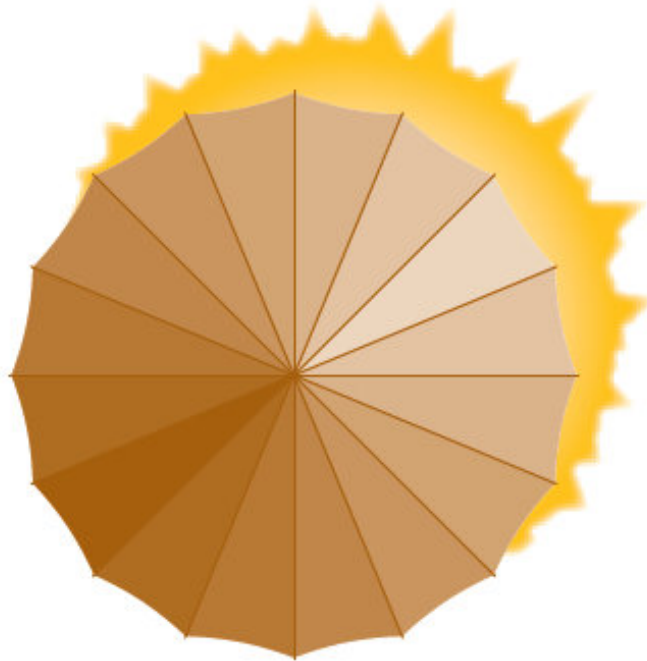
Description

EXTRASHADE SUN PROTECTION FOR RICH COMPLEXIONS BROAD SPECTRUM SPF 30
EXTRASHADE SUN PROTECTION FOR RICH COMPLEXIONS BROAD SPECTRUM SPF 30
DAILY DEFENSE HYDRATING SUNSCREEN LOTION WATER RESISTANT (80 MINUTES) •
PABA FREE FRAGRANCE FREE • OIL FREE • DYE FREE FACE AND BODY PROTECTION
FOR ACTIVE LIFESTYLE 4.0 Fl Oz (120ml)

Drug Facts

Extra Shade 1





EXTRASHADE

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BROAD SPECTRUM SPF 30

DAILY DEFENSE HYDRATING SUNSCREEN LOTION

WATER RESISTANT (80 MINUTES) • PABA FREE
FRAGRANCE FREE • OIL FREE • DYE FREE

FACE & BODY PROTECTION FOR ACTIVE LIFESTYLE

4.0 Fl Oz (120ml)

Extra Shade 2

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42338-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
HYDROXYETHYL CELLULOSE (140 MPAS AT 5%) (UNII: 8136Y38GY5)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
COCONUT (UNII: 3RT3536DHY)	
HEDYCHIUM CORONARIUM ROOT (UNII: 92A6N0IQN9)	
KIWI FRUIT (UNII: 71ES77LGJC)	
HIBISCUS ROSA-SINENSIS FLOWERING TOP (UNII: X9SED65819)	
PASSIFLORA EDULIS FLOWER (UNII: SY49TH8VUA)	
PLANTAGO MAJOR LEAF (UNII: 7DC28K241X)	
SAPONARIA OFFICINALIS ROOT (UNII: RI2K1BMA8B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42338-001-04	1 in 1 CARTON	01/06/2012	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/06/2012	

Labeler - Extrashade a Sub of Versatile Group (078350581)

Establishment

Name	Address	ID/FEI	Business Operations
Columbia Cosmetics Manufacturing, Inc.		068267863	manufacture(42338-001)

Revised: 11/2018

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