

**BEACH BREAK 2-IN-1 DAILY FACIAL MOISTURIZER SUNSCREEN SPF 30-
homosalate, octisalate, avobenzone, octocrylene lotion
EAI-JR 286**

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.

Beach Break 2-in-1 Daily Facial Moisturizer Sunscreen SPF 30

Active Ingredients Purpose

Homosalate 8% Sunscreen

Octisalate 5%

Avobenzone 3%

Octocrylene 2%

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
- Higher SPF gives more sunburn protection
- Retains SPF after 40 minutes activity in the water, sweating, or perspiring
- Provides high protection against sunburn

Keep out of reach of children

Stop use and ask a doctor if rash occurs

Warnings

- For external use only
- Do not use on broken or damaged skin
- When using this product keep out of eyes
- If product is swallowed, get medical help or contact a Poison Control Center right away

Directions

Apply liberally 15 minutes before sun exposure and at least every 2 hours

Reapply:

- After 40 minutes of swimming or sweating
- Immediately after towel drying
- **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 Broad Spectrum SPF of 15 or higher and other sun protection measures including:

- Limit time in the sun, especially from 10 a.m. to 2 p.m.
- Wear long-sleeve shirts, pants, hats, and sunglasses

- Children under 6 months: ask a doctor

Inactive Ingredients

Water (Aqua), Diisopropyl Adidpate, Dicaprylyl Ether, Pentylene Glycol, Stearyl/octyldodecyl Citrate Crosspolymer, Glycerin, Cetyl Alcohol, Potassium Cetyl Phosphate, Phenoxyethanol, Glyceryl Caprylate, Sodium Polyacrylate, Cetearyl Oliviate, Sorbitan Oliviate, Ferulic Acid, Tetrahexyldecyl Ascorbate, Caprylic/Capric Triglyceride, Limonene, Caprylhydroxamic Acid, Citrus Aurantium Dulcis (Orange) Peel Oil, Ethylhexylglycerin, Niacinamide, Sodium Gluconate, Aminomethyl Propanol, Citrus Aurantium Bergamia (Bergamot) Peel Oil, Jasminum Officinale (Jasmine) Extract, Linalool, Tocopherol, Eugenia Caryophyllus (Clove) Flower Extract, Lavandula Angustifolia (Lavender) Flower/Leaf/ Stem Extract, Vitis Vinifera (Grape) Fruit Extract, Glycine Soja (Soybean) Oil

Vertra

30

Beach Break Daily Facial Moisturizer

Broad Spectrum SPF 30

Water Resistant (40 minutes)

1.6 FL OZ / 45.36 mL

The Future Is Covered

vertra

Tested on Athletes
Not on Animals

INVISIBLE SUN PROTECTION
Your morning routine just got easier; this one-step daily moisturizer doubles as a sunscreen and will keep you protected wherever your day may take you. This formula, packed with hydrating niacinamide and soothing

Drug Facts	
Active Ingredients:	Purpose
Homosalate 8%	Sunscreen
Octisalate 5%	
Avobenzone 3%	
Octocrylene 2%	
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 • Higher SPF gives more sunburn protection • Retains SPF after 40 minutes activity in the water, sweating or perspiring • Provides high protection against 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	
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 and at least every 2 hours.	
Reapply: • After 40 minutes of swimming or sweating • Immediately after towel drying	
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 Broad Spectrum SPF of 15 or higher and other sun protection measures including: • Limit time in the sun, especially from 10 a.m. to 2 p.m. • Wear long-sleeve shirts, pants, hats and sunglasses • Children under 6 months: Ask a doctor	



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71014-038
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	

GLYCERIN (UNII: PDC6A3C0OX)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
SODIUM GLUCONATE (UNII: R6Q3791S76)
STEARYL/OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: PN88NW0KPK)
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)
CETEARYL OLIVATE (UNII: 58B69Q84JO)
FERULIC ACID (UNII: AVM951ZWST)
LINALOOL, (-)- (UNII: 3U21E3V8I2)
NIACINAMIDE (UNII: 25X5118RD4)
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
CETYL ALCOHOL (UNII: 936JST6JCN)
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SORBITAN OLIVATE (UNII: MDL271E3GR)
SOYBEAN OIL (UNII: 241ATL177A)
TOCOPHEROL (UNII: R0ZB2556P8)
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)
WINE GRAPE (UNII: 3GOV20705G)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71014-038-01	45.36 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	09/21/2022	

Labeler - EAI-JR 286 (827896718)