

OCEAN SEAS DERMATOLOGY ACNE TREATMENT CLEANSER- benzoyl peroxide solution

Coastal Carolinas Integrated Medicine

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.

Ocean Seas Dermatology Acne Treatment Cleanser

Active ingredient

Benzoyl Peroxide 2.5%

Purpose

Acne Treatment

Uses

for treatment of acne

Warnings

For external use only

Do Not Use

- if you have very sensitive skin • are sensitive to benzoyl peroxide.

When Using This Product

- avoid unnecessary sun exposure and use a sunscreen • avoid contact with the eyes, lips, mouth • avoid contact with hair and dyed fabrics, which may be bleached by this product • skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration

Stop and Ask a Doctor

- if irritation becomes severe.

Keep Out of Reach of Children

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

Directions

- Use every evening. Wet face with water. Apply a dime-sized amount into hands and gently wash your face; take care to avoid the eye area. Rinse well. • If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of product and ask a doctor.

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylates Crosspolymer, Aloe Barbadensis (Aloe Vera) Leaf Juice, * Camellia Sinensis (Green Tea) Leaf Extract, * Fragrance, Ginkgo Biloba (Ginkgo) Leaf Extract, * Glycerin, * Glycerin* (and) Cucumis Sativus (Cucumber) Fruit Extract, * Morus Alba (Mulberry) Bark Extract, * Sodium C14-16 Alpha Olefin Sulfonate, Sodium Hydroxide, Phenoxyethanol (and) Methylisothiazolinone, Water. *organic

Questions or Comments

1-844-88OCEAN (6-2326)

Package/Label Principal Display Panel

OCEAN SEAS™
DERMATOLOGY

ACNE
TREATMENT
CLEANSER

Distributed by OCEAN SEAS DERMATOLOGY
North Myrtle Beach, SC 29597



Label

OCEAN SEAS DERMATOLOGY ACNE TREATMENT CLEANSER

benzoyl peroxide solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69627-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	2.5 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CUCUMBER (UNII: YY7C30VXJT)	
GINKGO (UNII: 19FUJ2C58T)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MORUS ALBA BARK (UNII: 7O71A48NDP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69627-112-03	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	03/29/2016	

Labeler - Coastal Carolinas Integrated Medicine (007485606)

Registrant - Coastal Carolinas Integrated Medicine (007485606)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. J SkinClinic, Inc.		101497332	MANUFACTURE(69627-112) , ANALYSIS(69627-112) , LABEL(69627-112)