BILBOA CAPRI SUNSCREEN SPF 15 - avobenzone, octisalate, octocrylene, oxybenzone lotion Cadey S.r.l.

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.

Bilboa Capri Sunscreen Lotion SPF 15

Active Ingredients

Purpose Avobenzone 2%, Octisalate 5%, Octocrylene 3%, Oxybenzone 2% Sunscreen

Uses

- Helps prevent sunburn

- Higher SPF gives more sunburn protection

- Provides moderate protection against sunburn

- Retains SPF after 40 minutes of activity in the water

Warnings For external use only

UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen

When using this product - keep out of eyes. Rinse with water to remove

Stop use and ask a doctor if - rash or irritation develops and lasts

Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Apply generously and evenly before sun exposure and as needed
- Children under 6 months of age: ask a doctor
- Reapply as need or after toweling drying, swimming, or perspiring

Inactive ingredients Water, Butyloctyl Salicylate, Dicaprylyl Carbonate, Stearyl/octadodecyl Citrate Crosspolymer, Ethylhexyl Methoxycrylene, Pentaerythrityl Distearate, Dimethicone, Phenoxyethanol, Sodium Polyacrylate, Sodium Stearoyl Glutamate, Fragrance, Ethylhexylglycerin, Tropolone, Disodium Edta, Tetrasodium Edta, Benzyl Salicylate, Geraniol, Aloe Barbadensis Leaf Extract, Coumarin, Maltodextrin.

Questions? visit www.cadeyusa.com

Bilboa Capri, inspired by one of the best-known Mediterranean islands, comes from Cadey's Italian experience. The 15 Lotion provides UVA/UVB sunscreen protection against sunburn. It is also enriched with moisturizes and soothing Aloe and Vitamin E. Dermatologically tested - Aminobenzoic acid (PABA) - free

Made In Italy Manufactured for Cadev Srl Distributed by RBY LLC 5816 Avian Place Concord NC 28025

cadey

BILBOA Caprl Sunscreen Lotion Broad spectrum UVA/UVB protection Moisturizing and soothing

formula 15 SPF Water-resistant With Aloe 6.76 fl oz (200 ML) Made In Italy Manufactured for Cadey Srl Distributed by RBY LLC 5816 Avian Place Concord NC 28025 cadey 8 51055 00300 9



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Edta, Tetrasodium Edta, Ben Barbadensis Leaf Extract, Co Questions? visit www.bilbo	oacapri.com
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BILBOA CAPRI SUNSCREEN SPF 15 avobenzone, octisalate, octocrylene, oxybenzone lotion **Product Information** NDC:76070-100 **Product Type** HUMAN OTC DRUG Item Code (Source) **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Ingredient Name** Basis of Strength Strength AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) AVOBENZONE 2 mL in 100 mL**OCTISALATE** (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) 5 mL in 100 mL OCTISALATE **OCTOCRYLENE** (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) OCTOCRYLENE 3 mL in 100 mL **OXYBENZONE** (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y) OXYBENZONE 2 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)				
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
TROPOLONE (UNII: 7L6DL16P1T)				
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)				
EDETATE SODIUM (UNII: MP1J8420LU)				
BENZYL SALICYLATE (UNII: WAO5MNK9TU)				
GERANIOL (UNII: L837108USY)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
COUMARIN (UNII: A4VZ22K1WT)				

MALTODEXTRIN (UNII: 7CVR7L4A2D)							
Packaging							
# Item Code	Package Description	Marketing Start Date		Ma	Marketing End Date		
1 NDC:76070-100-06	1 in 1 PACKAGE						
1	200 mL in 1 BOTTLE						
Marketing Information							
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date		
OTC monograph final	part352		03/08/2011				

Labeler - Cadey S.r.l. (428414261)

Establishment							
Name	Address	ID/FEI	Business Operations				
Safosa S.p.A.		429518632	manufacture				

Revised: 5/2011

Cadey S.r.l.