

BILBOA CAPRI SUNSCREEN SPF 50 PLUS - avobenzene, homosalate, 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 50 Plus

Active Ingredients	Purpose
Avobenzene 3%, Homosalate 13%, Octisalate 3%, Octocrylene 2%, Oxybenzone 6%	Sunscreen

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Provides high 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, Ethylhexyl Methoxycrylene, Dicaprylyl Carbonate, Stearyl/octadodecyl Citrate Crosspolymer, Pentaerythrityl Distearate, Dimethicone, Phenoxyethanol, Sodium Stearoyl Glutamate, Sodium Polyacrylate, 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 50+ 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 Cadey Srl

Distributed by RBY LLC

5816 Avian Place

Concord NC 28025

cadey

BILBOA Capri Sunscreen Lotion Broad spectrum UVA/UVB protection Moisturizing and soothing formula 50+ 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 00304 7



Sunscreen Lotion

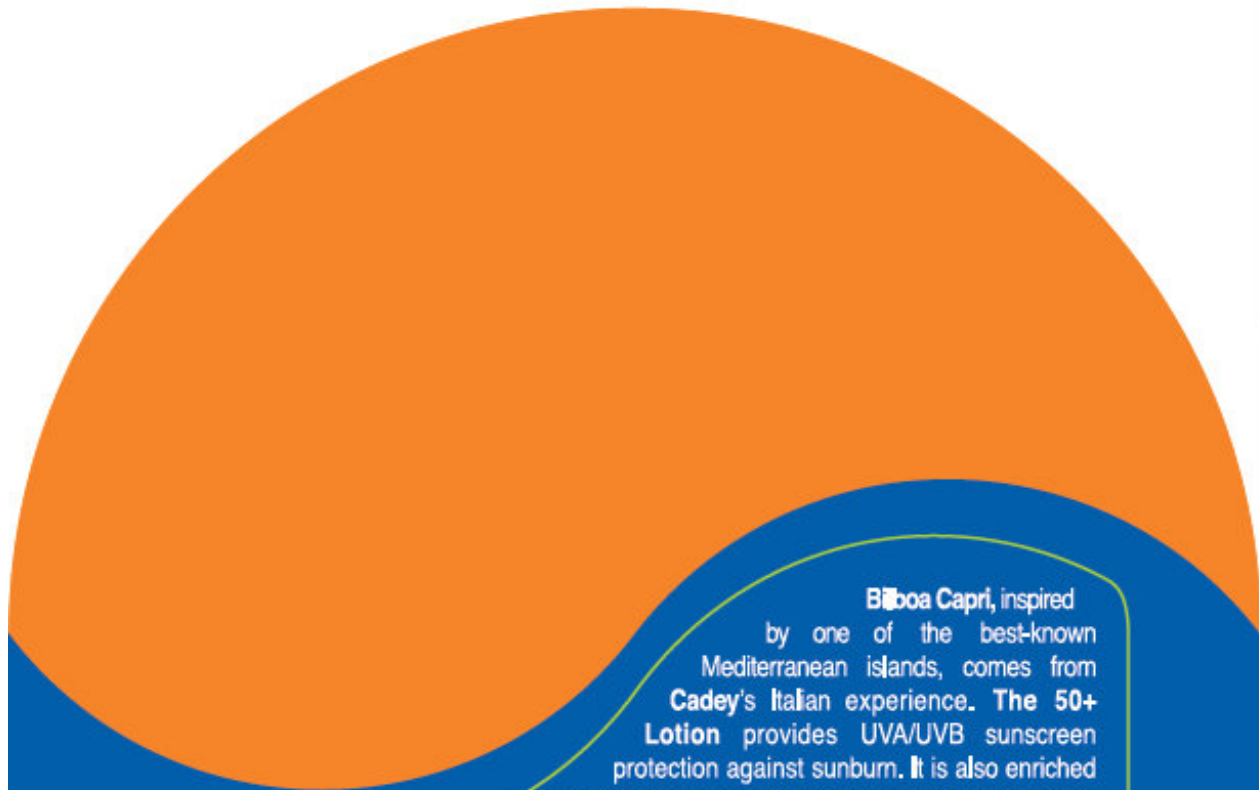
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Drug Facts

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Questions? visit www.bilboacapri.com

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76070-120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 mL in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 mL in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 mL in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TROPOLONE (UNII: 7L6DL16P1T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EDETATE SODIUM (UNII: MP1J8420LU)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
GERANIOL (UNII: L837108USY)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COUMARIN (UNII: A4VZ22K1WT)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76070-120-06	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