

**BILBOA CAPRI SUNSCREEN SPF 30 - 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 30**

| Active Ingredients   | Purpose   |
|--|-----------|
| Avobenzene 3%, Homosalate 13%,<br>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, Dicaprylyl Carbonate, Ethylhexyl Methoxycrylene, 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](http://www.cadeyusa.com)

Bilboa Capri, inspired by one of the best-known Mediterranean islands, comes from Cadey's Italian experience. The 30 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 30 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 00302 3



# Sunscreen Lotion

**Broad spectrum UVA/UVB protection**

Moisturizing and soothing formula

Water-resistant

With Aloe

**6.76 fl oz (200 ML)**



Bilboa Capri, inspired by one of the best-known Mediterranean islands, comes from Cadey's Italian experience. The 30 Lotion provides UVA/UVB sunscreen protection against sunburn. It is also enriched with moisturizing and soothing Aloe and Vitamin E.

Dermatologically tested • Aminobenzoic acid (PABA) - free

## **Drug Facts**

### **Active Ingredients**

Avobenzone 3%, Homosalate 13%,

### **Purpose**

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

**Questions?** visit [www.bilboacapri.com](http://www.bilboacapri.com)

**Made In Italy**

Manufactured for Cadey Srl  
Distributed by RBY LLC  
5816 Avian Place  
Concord NC 28025



8.27 x 11.69 in

**BILBOA CAPRI SUNSCREEN SPF 30**

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:76070-110 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

| Ingredient Name                                 | Strength |
|---|----------|
| <b>WATER</b> (UNII: 059QF0K00R)                 |          |
| <b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3) |          |
| <b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)  |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)           |          |
| <b>PHENOXYETHANOL</b> (UNII: HE492ZZ3T)         |          |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)    |          |
| <b>TROPOLONE</b> (UNII: 7L6DL16P1T)             |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)      |          |
| <b>EDETATE SODIUM</b> (UNII: MP1J8420LU)        |          |
| <b>BENZYL SALICYLATE</b> (UNII: WAO5MKN9TU)     |          |
| <b>GERANIOL</b> (UNII: L837108USY)              |          |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)        |          |
| <b>COUMARIN</b> (UNII: A4VZ22K1WT)              |          |
| <b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)          |          |

**Packaging**

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:76070-110-06 | 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         |