

**VILLA FLORIANI MINT PURIFYING DAY SPF 20- avobenzone, octocrylene, octinoxate, and octisalate lotion**

**Originalia srl**

*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.*

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**Villa Floriani Mint Purifying Day Lotion SPF 20**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 3%	Sunscreen
Octinoxate 3.5%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 9%	Sunscreen

**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

**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 product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- apply liberally 15 minutes before sun exposure
- apply to all skin exposed to the sun
- children under 6 months: Ask a doctor

**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 a broad spectrum SPF of 15 or higher and other sun protection measures including:

- ◦ limit time in the sun, especially from 10 a.m. - 2 p.m.
- ◦ wear long-sleeve shirts, pants, hats, and sunglasses
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating

**Other information**

- protect this product from excessive heat and direct sun
- you may report a serious adverse reaction to this product to: Report Reaction, LLC PO Box 22 Plainsboro, NJ 08536-0222

## **Inactive ingredients**

Water, C12-15 Alkyl Benzoate, Sorbitol, Cetearyl Isononanoate, Butylene Glycol, Isononyl Isononanoate, Dicaprylyl Carbonate, Simmondsia Chinensis (Jjoba) Seed Oil, Macadamia Ternifolia Seed Oil, Fomes Officinalis (Mushroom) Extract, Olea Europaea (Olive) Oil Unsaponifiables, Malva Sylvestris (Mallow) Flower/Leaf Extract, Arctium Lappa Root Extract, Mentha Piperita (Peppermint) Leaf Extract, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Helianthus Annuus (Sunflower) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Silica, Cetareth-20, Cetearyl Alcohol, Cetareth-12, Cetyl Palmitate, Glycerin, Glyceryl Stearate, Sodium Polyacrylate, Citric Acid, Sodium Phytate, Chlorphenesin, PVP, Disodium EDTA, Ethylhexylglycerin, Phenoxyethanol, Dehydroacetic Acid, Benzyl Alcohol, Sodium Benzoate, Potassium Sorbate, Limonene, Butylphenyl Methylpropional, Hexyl Cinnamal, Eugenol, Citronellol, Fragrance.

## **PRINCIPAL DISPLAY PANEL - 50 mL Bottle Box**

**VILLA**

**FLORIANI**

PHYTO-CURACTIVE SKINCARE™

PureActive

BALANCE & CONTROL

Mint Purifying

Day Lotion

BROAD SPECTRUM

SPF 20

SUNSCREEN

normal / oily

50 mL 1.69 Fl. Oz.

normal / oily

**Mint Purifying Day Lotion**

For instant hydration and a matt-looking finish, this refreshing, light-textured Day Lotion is a skin sensation. Thanks to phyto-science technology, Villa Floriani's effective Phyto-Curactive™ blend of natural, bio-certified extracts helps purify and restore the skin's natural balance. Oily to blemish-prone skin is left feeling beautifully soft and protected.

- With SPF 20 for protection against UVA and UVB damage.
- Peppermint, Witch Hazel, Olive & Macadamia help purify, soften and freshen the skin's surface.
- Fomes Officinalis (Mushroom) pulp extract helps restore the skin's natural balance.

Made in Italy  
Originalitalia srl - 36030 Caldogno (VI) Italy  
www.villafloiriani.com



**Drug Facts** (continued)

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PureActive  
BALANCE & CONTROL

Mint Purifying  
Day Lotion

BROAD SPECTRUM  
SPF 20  
SUNSCREEN

normal / oily

50 mL 1.69 Fl. Oz.

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  - wear long-sleeve shirts, pants, hats, and sunglasses
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  - use a water-resistant sunscreen if swimming or sweating

CONTINUE ➡



# VILLA FLORIANI MINT PURIFYING DAY SPF 20

avobenzone, octocrylene, octinoxate, and octisalate lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68586-219
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	90 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	35 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EUGENOL (UNII: 3T8H1794QW)	
LARICIFOMES OFFICINALIS FRUITING BODY (UNII: 7IFM8431X3)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

MACADAMIA OIL (UNII: 515610SU8C)	
MALVA SYLVESTRIS FLOWERING TOP (UNII: X1U1U0N90J)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
ROSEMARY (UNII: IJ67X351P9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
JOJOBA OIL (UNII: 724GKU717M)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SORBITOL (UNII: 506T60A25R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68586-219-01	1 in 1 BOX	08/22/2016	
1		50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:68586-219-02	5 mL in 1 PACKET; Type 0: Not a Combination Product	08/22/2016	
3	NDC:68586-219-03	1 in 1 BOX	03/15/2019	
3		20 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/22/2016	

**Labeler** - Originalia srl (441072253)

Revised: 1/2019

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