

VILLA FLORIANI CHAMOMILE CALMING 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.

Villa Floriani Chamomile Calming Day Lotion SPF 20

Drug Facts

Active ingredients	Purpose
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, Glycerin, Isononyl Isononanoate, Peucedanum Ostruthium Leaf Extract, Centella Asiatica Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Plantago Major Leaf Extract, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Helianthus Annuus (Sunflower) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Ammonium Glycyrrhizate, Olive Glycerides, Caffeine, Dicaprylyl Ether, Olea Europaea (Olive) Oil Unsaponifiables, Sodium Polyacrylate, Cetareth-20, Cetearyl Alcohol, Mannitol, Silica, Glyceryl Stearate, Sodium PCA, PVP, Cetareth-12, Cetyl Palmitate, Chlorphenesin, Zinc Gluconate, Sodium Phytate, Disodium EDTA, Benzyl Alcohol, Citric Acid, Ethylhexylglycerin, Phenoxyethanol, Dehydroacetic Acid, Sodium Benzoate, Sodium Dehydroacetate, Potassium Sorbate, Benzyl Salicylate, Limonene, Hexyl Cinnamal, Hydroxycitronellal, Citronellol, Eugenol, Cinnamyl Alcohol, Benzyl Benzoate, Linalool, Butylphenyl Methylpropional, Isoeugenol, Fragrance.

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Box

VILLA

FLORIANI

PHYTO-CURACTIVE SKINCARE™

CalmActive

SOOTHE & RESTORE

Chamomile Calming

Day Lotion

BROAD SPECTRUM

SPF 20

SUNSCREEN

sensitive

50 mL 1.69 Fl. Oz.

sensitive

Chamomile Calming Day Lotion

Calm and ultra-nourish sensitive skin for a more radiant look. Villa Floriani's unique Phyto-Curactive™ blend of natural, bio-certified extracts helps this rich yet light-textured moisturizing lotion replenish and maintain skin's moisture level throughout the day. These plant active synergies also help to calm irritated skin, protect against environmental damage and aid in slowing down the signs of aging.

- With SPF 20 for protection against UVA and UVB damage.
- An infusion of Chamomile calms reddened, irritated skin, helping to increase its sensitivity tolerance against environmental damage.
- Hydrating Jojoba, Sweet Almond oils, natural sodium PCA and Olive Oil nourish & protect by replacing lost moisture.

Made in Italy

Originalita s.r.l. - 36030 Caldogno (VI) Italy

www.villafloriani.com



Drug Facts

(continued)

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CalmActive
SOOTHE & RESTORE

Chamomile Calming
Day Lotion

BROAD SPECTRUM
SPF 20
SUNSCREEN

sensitive

50 mL 1.69 Fl. Oz.

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VILLA FLORIANI CHAMOMILE CALMING DAY SPF 20

avobenzone, octocrylene, octinoxate, and octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68586-220
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: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SORBITOL (UNII: 506T60A25R)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
PEUCEDANUM OSTRUTHIUM LEAF (UNII: 86P27YRR6Y)	
CENTELLA ASIATICA LEAF (UNII: 6810070TYD)	
CHAMOMILE (UNII: FGL3685T2X)	
PLANTAGO MAJOR LEAF (UNII: 7DC28K241X)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ROSEMARY (UNII: IJ67X351P9)	
JOJOBA OIL (UNII: 724GKU717M)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
CAFFEINE (UNII: 3G6A5W338E)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
MANNITOL (UNII: 3OWL53L36A)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
CETEARETH-12 (UNII: 7V4MR24V5P)	

CETYL PALMITATE (UNII: 5ZA2S6B08X)
CHLORPHENESIN (UNII: I670DAL4SZ)
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)
PHYTATE SODIUM (UNII: 88496G1ERL)
EDETATE DISODIUM (UNII: 7FLD91C86K)
BENZYL ALCOHOL (UNII: LKG8494WBH)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
DEHYDROACETIC ACID (UNII: 2KAG279R6R)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
EUGENOL (UNII: 3T8H1794QW)
CINNAMYL ALCOHOL (UNII: SS8YOP444F)
BENZYL BENZOATE (UNII: N863NB338G)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
ISOEUGENOL (UNII: 5M0MWY797U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68586-220-01	1 in 1 BOX	11/07/2016	
1		50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:68586-220-03	1 in 1 BOX	08/15/2018	
2		20 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
3	NDC:68586-220-02	5 mL in 1 PACKET; Type 0: Not a Combination Product	11/07/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/07/2016	

Labeler - Originalia srl (441072253)