

**VILLA FLORIANI ALOE ULTRA-HYDRATING DAY SPF 20- avobenzone, octinoxate, octisalate, octocrylene 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 ALOE ULTRA-HYDRATING DAY LOTION SPF 20**

**Drug Facts**

**Active ingredients**

Avobenzone 3%

Octinoxate 3.5%

Octisalate 5%

Octocrylene 9%

**Purpose**

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**

Aqua (Water), C12-15 Alkyl Benzoate, Sorbitol, Cetearyl Isononanoate, Isononyl Isononanoate, Argania Spinosa Kernel Oil, Persea Gratissima (Avocado) Oil, Rosa Moschata Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Sodium Hyaluronate, Althaea Officinalis Root Extract, Rosa Canina Fruit Extract, Tilia Tomentosa Extract, Aloe Barbadensis Leaf Juice, Evernia Prunastri (Oakmoss) Extract, Phospholipids, Sphingolipids, Spirulina Platensis Extract, Trehalose, Palmitoyl Tripeptide-5, Serine, Algin, Pullulan, Cetareth-20, Cetearyl Alcohol, Cetareth-12, Cetyl Palmitate Sodium Polyacrylate, Glyceryl Polyacrylate, Dicaprylyl Carbonate, PVP, Sodium Phytate, Glyceryl Stearate, Glycerin, Pentylene Glycol, Caprylyl Glycol, Disodium Phosphate, Disodium EDTA, Potassium Phosphate, Silica, Urea, Citric Acid, Benzyl Alcohol, Sodium Benzoate, Potassium Sorbate, Chlorphenesin, Ethylhexylglycerin, Phenoxyethanol, Dehydroacetic Acid, Linalool, Limonene, Coumarin, Citral, Parfum (Fragrance).

**Company Information**

Made in Italy

Originalitalia srl - 36030 Caldogno (VI) Italy

[www.villafloriani.com](http://www.villafloriani.com)

**Product Packaging**

HydraActive

NOURISH & REPLENISH

Aloe Ultra-Hydrating Day Lotion

BROAD SPECTRUM

SPF 20

SUNSCREEN

normal/dry

50 mL 1.69 Fl. Oz.

**Aloe Ultra-Hydrating Day Lotion**

For instant hydration and a radiant finish, this moisturizing, light-textured antioxidant Day Lotion with SPF 20 is a skin sensation. Villa Floriani's effective Phyto-Curactive™ blend of Hyaluronic Acid, oils and bio-certified extracts uses phyto-science technology to help nourish and plump the skin. Coupled with the regenerating properties of Aloe Vera, dry and dehydrated skin is left feeling beautifully soft and protected against harmful UV rays and pollution.

- Aloe Vera, Rose Hip and Linden extracts help regenerate skin cells
- Avocado, Argan and Musk Rose oils soften and nourish the skin
- SPF 20 protects against UVA and UVB damage

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**Drug Facts** (continued)

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HydraActive  
NOURISH & REPLENISH

Aloe Ultra-Hydrating  
Day Lotion

BROAD SPECTRUM  
SPF 20  
SUNSCREEN

normal / dry

50 mL 1.69 Fl. Oz.

**Drug Facts**

| Active ingredients | Purpose   |
|--------------------|-----------|
| Avobenzene 3%      | Sunscreen |
| Octinoxate 3.5%    | Sunscreen |
| Octisalate 5%      | Sunscreen |
| Octocrylene 9%     | Sunscreen |

**Uses**

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CONTINUE ➡

**VILLA FLORIANI ALOE ULTRA-HYDRATING DAY SPF 20**

avobenzene, octinoxate, octisalate, octocrylene lotion

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68586-225 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength      |
|---|-------------------|---------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)   | OCTINOXATE        | 35 mg in 1 mL |
| <b>AVOBENZENE</b> (UNII: G63QQF2NOX) (AVOBENZENE - UNII:G63QQF2NOX)   | AVOBENZENE        | 30 mg in 1 mL |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 90 mg in 1 mL |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 50 mg in 1 mL |

**Inactive Ingredients**

| Ingredient Name   | Strength |
|---|----------|
| POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)        |          |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)                  |          |
| CETEARETH-12 (UNII: 7V4MR24V5P)                         |          |
| POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)       |          |
| SODIUM BENZOATE (UNII: OJ245FE5EU)                      |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                       |          |
| TILIA TOMENTOSA WHOLE (UNII: 744437C6KV)                |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                       |          |
| SPIRULINA PLATENSIS (UNII: 9L3TIHIUUE)                  |          |
| PALMITOYL TRIPEPTIDE-5 (UNII: 2A3916MQHO)               |          |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)                |          |
| CETEARYL ISONONANOATE (UNII: P5O01U99NI)                |          |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH)                   |          |
| DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)                 |          |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)                |          |
| PENTYLENE GLYCOL (UNII: 50C1307PZG)                     |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                      |          |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)              |          |
| BENZYL ALCOHOL (UNII: LKG8494WBH)                       |          |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)                   |          |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) |          |
| EDETATE DISODIUM (UNII: 7FLD91C86K)                     |          |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4)                    |          |
| DEHYDROACETIC ACID (UNII: 2KAG279R6R)                   |          |
| WATER (UNII: 059QF0KO0R)                                |          |
| SORBITOL (UNII: 506T60A25R)                             |          |
| AVOCADO OIL (UNII: 6VNO72PFC1)                          |          |
| ROSA MOSCHATA SEED OIL (UNII: T031ZE559T)               |          |
| PULLULAN (UNII: 8ZQ0AYU1TT)                             |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                      |          |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)              |          |
| SUNFLOWER OIL (UNII: 3W1JG795Y)                         |          |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62)                    |          |
| EVERNIA PRUNASTRI (UNII: O3034Q5AHK)                    |          |
| SODIUM ALGINATE (UNII: C269C4G2ZQ)                      |          |
| GLYCERIN (UNII: PDC6A3C0OX)                             |          |
| LIMONENE, (+)- (UNII: GFD7C86Q1W)                       |          |
| CITRAL (UNII: T7EU0O9VPP)                               |          |
| UREA (UNII: 8W8T17847W)                                 |          |
| LINALOOL, (+/-)- (UNII: D81QY6I88E)                     |          |
| COUMARIN (UNII: A4VZ22K1WT)                             |          |
| TREHALOSE (UNII: B8WCK70T7I)                            |          |
| SERINE (UNII: 452VLY9402)                               |          |
| PHYTATE SODIUM (UNII: 88496G1ERL)                       |          |
| CHLORPHENESIN (UNII: I670DAL4SZ)                        |          |
| ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)                |          |
| ARGAN OIL (UNII: 4V59G5UW9X)                            |          |
| ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)             |          |
| ROSA CANINA FRUIT (UNII: 3TNW8D08V3)                    |          |

**Packaging**

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68586-225-01 | 1 in 1 BOX  | 06/07/2019           |                    |
| 1 |                  | 50 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 not final | part352                                  | 06/07/2019           |                    |

**Labeler** - Originalia srl (441072253)**Registrant** - Originalia srl (441072253)

Revised: 6/2019

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