

VMV HYPOALLERGENICS ARMADA 30- ensulizole, octisalate, titanium dioxide, zinc oxide cream

SKIN SCIENCES LABORATORY INC.

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.

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Direction), decrease the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only

Do not use on damaged skin or broken skin

Stop use and ask doctor if rash occurs

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children, if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure. Use daily, both indoors and outdoors.
- Use water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10a.m. to 2 p.m.
 - Wear long-sleeved shirt, pants, hats and sunglasses.
 - Children under 6 months: Ask a doctor.

Other Informations

- Protect the product in this container from excessive heat and direct sun.
- Before use, test a tiny amount on skin (we omit allergens, but you may be sensitive to an ingredient that is not an allergen).
- Introduce new skin products one at a time, with at least 3 days in between.
- Do not (re) introduce removed portions of product or other substances into container

Inactive Ingredients

Aluminum Hydroxide, Aqua/Water/Eau, Butylene Glycol, Camellia Sinensis Leaf Extract, Caprylic/Capric Triglyceride, Caprylyl Glycol, Cyclopentasiloxane, Glyceryl Laurate, Hydrogen Dimethicone, Octyldodecyl Neopentanoate, PEG-10 Dimethicone, Sodium Bicarbonate, Sodium Phytate, Steareth-2, Steareth-21, Zirconium Dioxide.

Principal Display Panel

<p>DURING ACTIVE FLARE-UPS: As skin can be irritated even with plain water during flare-ups, do not use this or any product on skin during a flare-up: consult your dermatologist or wait until the flare-up subsides.</p> <p>IMPORTANT: For external use only on specified areas as directed. Stop use and consult a doctor in the unlikely event of discomfort or sensitivity. If contact with eyes occurs, flush out with plenty of water. Keep out of reach of children. While safe for its intended use, ingesting large amounts of this product is potentially harmful — if this happens, get medical help right away.</p>  <p>4806027703100</p> <p>BEST USED BY 10/2011 LOT 391</p>	<p>VMV HYPOALLERGENICS <i>validated hypoallergenic, randomized, blinded, published & awarded clinical studies since 1979</i></p> <p>ARMADA</p>  <p>INDOOR-OUTDOOR SKIN COVER 30</p> <p>BROAD SPECTRUM SPF 30</p> <p><u>sun + light screen for face + body</u> UVA, UVB, Visible + Infrared Light</p> <p>Validated Hypoallergenic: VH -7676 sans all common allergens: extended allergen series North American Contact Dermatitis Group + standard allergen series European Surveillance System of Contact Allergies</p> <p>SPF: 30. PFA: 60. PFV: 3. PFI: 5. Critical Wavelength: 370. UVA:UVB Ratio = 0.36:0.64.</p> <p>100% All-Types-Of-Fragrance-Free.</p> <p>100% Dye-Phthalate-PABA-Paraben + Preservative-Free.</p> <p>Usage, Patch + Clinically-Tested (in vivo + in vitro). For All Skin Types.</p> <p>Non-Comedogenic. Non-Drying.</p>	<p>protection solaire à large spectre <small>contient les rayons de lumière visible, infrarouges, UVA + UVB SPF 30</small></p> <p>crema solare protettiva <small>SPF 30</small></p> <p>protector solar de amplio espectro <small>contiene rayos de luz infrarrojos, visibles, UVA + UVB SPF 30</small></p> <p>Powerful protection against indoor and outdoor UVA, UVB, Infrared + Visible rays and light from the sun, indoor lights and heat sources. Can help prevent sun-induced skin cancer, hyperpigmentations and photoaging. Allows skin to brighten naturally. Also for skin that is photosensitive, recovering from some procedures, or undergoing active therapies. Comfortable and pore-friendly. With calming and moisturizing monoglycerides and antioxidants.</p> <p>Choose this Armada: if you have mild melasma or want less opacity / a very lightweight cream.</p> <p>For children under 6-months old: ask your doctor or use Armada Baby.</p> <p>READ BROCHURE + DRUG FACTS ON BOX FOR MORE INSTRUCTIONS.</p> <p>See Brochure, Voir Brochure, Vedere Brochure, Ver Brochure. Read all information in brochures, online + on container. As with all things skin, consult your dermatologist. — © VMV USA Ltd. Dist. - New York, NY USA. - Berant Srd Palazo Bonomo, Via San Carlo 52, Ancona Italy. - Made in the Philippines exclusively for VMV Hypoallergenic's 1983 — SKIN01.118183 / HELP: vmvhypoallergenic.com</p>	<p>DrugFacts</p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Ensulizole - 4.0%</td> <td rowspan="4">Sunscreen</td> </tr> <tr> <td>Octisalate - 3.0%</td> </tr> <tr> <td>Titanium Dioxide - 0.6%</td> </tr> <tr> <td>Zinc Oxide - 23.0%</td> </tr> </tbody> </table> <p>Uses n Helps prevent sunburn. n 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.</p> <p>Warnings For external use only Do not use on damaged or broken skin Stop use and ask doctor if rash occurs When using this product keep out of eyes. Rinse with water to remove. Keep out of reach of children if swallowed, get medical help or contact a Poison Control Cent. right away.</p> <p>Directions n Apply liberally 15 minutes before sun exposure. Use daily, both indoors and outdoors. n Use a water resistant sunscreen if swimming or sweating. n Reapply at least every 2 hours. n Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measure including: n limit time in the sun, especially from 10 a.m. to 2 p.m. n wear long-sleeved shirts, pants, hats, and sunglasses. n Children under 6 months: Ask a doctor.</p> <p>Other information n Protect the product in this container from excessive heat and direct sun. n Before use, test a tiny amount on skin (we omit allergens, but you may be sensitive to an ingredient that is not an allergen). n Introduce new skin products one at a time, with at least 3 days in between. n Do not (re)introduce removed portions of product or other substances into container</p> <p>Inactive ingredients Aluminum Hydroxide, Aqua/Water/Eau, Butylene Glycol, Camellia Sinensis Leaf Extract, Caprylic/Capric Triglyceride, Caprylyl Glycol, Cyclopentasiloxane, Glycerol Laurate, Hydroxy Dimethicone, Octyldodecyl Neopentanoate, PEG-10 Dimethicone, Sodium Bicarbonate, Sodium Phytate, Steareth-2, Steareth-21, Zirconium Dioxide.</p>	Active Ingredients	Purpose	Ensulizole - 4.0%	Sunscreen	Octisalate - 3.0%	Titanium Dioxide - 0.6%	Zinc Oxide - 23.0%
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VMV HYPOALLERGENICS
 validated hypoallergenic. randomized, blinded,
 published & awarded clinical studies, since 1979.
 ARMADA 30
 INDOOR-
 OUTDOOR
 SKIN
 COVER
 BROAD SPECTRUM SPF 30
 sun + light screen
 for face + body
 UVA, UVB, Visible + Infrared Light
 Validated Hypoallergenic:
 VH -76/76
 sans all common allergens:
 extended allergen series
 North American Contact Dermatitis
 Group + Standard allergen series

European Surveillance System of

Contact Allergies

SPF: 30. PFA: 60. PFV: 3. PFI:

5. Critical Wavelength: 370.

UVA:UVB Ratio = 0.36:0.64.

100% All-Types-Of-Fragrance-Free.

100% Dye-Phthalate-PABA-

Paraben + Preservative-Free.

Usage, Patch + Clinically-

Tested (in vivo + in vitro).

Non-Comedogenic. Non-Drying.

For All Skin Types.

85g (3.0 Oz.) - 85g e

Active Ingredient

Ensulizole

Octisalate

Titanium Dioxide

Zinc Oxide

Active Ingredient

Ensulizole - 4.0%

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69774-536
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.6 g in 85 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 85 g
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	4 g in 85 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	23 g in 85 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69774-536-63	1 in 1 CARTON	01/01/2015	
1		1 g in 1 TUBE; 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	01/01/2015	

Labeler - SKIN SCIENCES LABORATORY INC. (718777360)

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SKIN SCIENCES LABORATORY INC.