

ALUMIER MD SHEER HYDRATION- titanium dioxide, zinc oxide lotion
Alumier Labs

Alumier MD Sheer Hydration

Drug Facts

Active Ingredients

Titanium Dioxide 7%

Zinc Oxide 6.28%

Purpose

Sunscreen

Use

- helps prevent sunburn

Warnings

- **For external use only.**

When using this product

- do not use on damaged or broken skin
- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if you develop severe irritation, burning or itching of the skin, hives, swelling of eyes and mouth, blistering or difficulty breathing

Keep out of reach of children. If swallowed, call a Poison Control Centre or get medical help right away.

Directions

- apply liberally/generously (and evenly) 15 minutes before sun exposure
- reapply at least every 2 hours
- for use on children less than 6 months of age, consult a health care practitioner
- **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 value 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-sleeved shirts, pants, hats and sunglasses
- use a water resistant sunscreen if swimming or sweating

Other Information

- Do not use if security seal is broken or missing.
- You may report a serious adverse reaction event from using this product to: Alumier Labs Inc., 550 Cochituate Road, Suite 25, Framingham, MA 01701

Inactive Ingredients

Water/Aqua/Eau, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Propanediol, Butyloctyl Salicylate, Cetearyl Alcohol, Aluminium Stearate, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Lecithin (Syn. Phosphatidylcholine), Vitis Vinifera Seed Extract, Resveratrol, Glutathione, Tocopheryl Acetate, Magnesium Ascorbyl Phosphate, Acacia Senegal Gum, Synthetic Wax, Polyhydroxysteric Acid, Cetareth-20, Alumina, Microcrystalline Cellulose, Triethoxycaprylylsilane, Xanthan Gum, Cellulose Gum, C20-40 Pareth-10, Hydroxyethyl Behenamidopropyl Dimonium Chloride, Polyquaternium-67, Disodium EDTA, Ethylhexylglycerin, Phenoxyethanol.

Product Packaging - 236 mL

Alumier MD

Sheer Hydration

Broad Spectrum SPF 40

MOISTURIZING SUNSCREEN LOTION

UNTINTED

NPN 80064932

236 mL / 8 fl oz

<p style="text-align: center;">Alumier[®] ALUMIER EUROPE LTD. 3 ST. FREDERICK STREET VALETTA VLT 140, MALTA WWW.ALUMIERMD.COM EUROPE • UNITED STATES • CANADA UNITED KINGDOM DISTRIBUTED IN CANADA BY: ALUMIER LABS INC. 436 LIMESTONE CRESCENT TORONTO, ON, M3J 2S4 DISTRIBUTED IN THE USA BY: ALUMIER LABS INC. 550 COCHITUATE ROAD, SUITE 25 FRAMMINGHAM, MA 01701 MANUFACTURED IN CANADA UNDER LICENSE FROM ALUMIER EUROPE LTD. FABRIQUÉ AU CANADA SOUS LICENCE OCTROIÉE PAR ALUMIER EUROPE LTD.</p>	<p>Notice</p> <p>Ingrédients actifs Utilisation Dioxyde de titane 7 %.....Crème solaire Oxyde de zinc 6,28 %.....Crème solaire</p> <p>Usage ■ protège contre les coups de soleil</p> <p>Avertissements ■ Usage externe uniquement.</p> <p>Quand on utilise ce produit ■ ne pas utiliser sur les peaux endommagées ou abîmées ■ éviter le contact avec les yeux ; en cas de contact, rincer abondamment à l'eau</p> <p>Arrêtez l'utilisation et demandez à un docteur si vous développez de l'urticaire, un gonflement des yeux ou de la bouche, des cloques ou si vous avez des difficultés à respirer</p> <p>Garder hors de portée des enfants. En cas d'ingestion, contacter un centre antipoison ou appeler un médecin immédiatement.</p> <p>Conseils d'utilisation ■ appliquer abondamment (et régulièrement) 15 minutes avant l'exposition au soleil. ■ appliquer de nouveau au moins toutes les 2 heures ■ pour une utilisation sur des enfants de moins de 6 mois, consulter un professionnel de la santé ■ Mesures de Protection Solaire : L'exposition au soleil augmente le risque de cancer et de vieillissement précoce de la peau. Pour diminuer ce risque, utiliser régulièrement une crème solaire large spectre d'une valeur FPS de 15 ou plus, et d'autres mesures de protection solaire, telles que : limiter la durée d'exposition au soleil, en particulier entre 10 h et 14 h - porter des hauts à manches longues, des pantalons, des chapeaux et des lunettes de soleil ■ utiliser une crème solaire résistante à l'eau en cas de baignade ou de transpiration.</p> <p>Autres Information ■ Ne pas utiliser si le sceau de sécurité est endommagé ou manquant. ■ Vous pouvez signaler toute réaction indésirable liée à l'utilisation de ce produit à : Alumier Labs Inc., 550 Cochituate Road, Suite 25, Frammingham, MA 01701</p>	<p style="text-align: center;">Alumier^{MD}</p> <p style="text-align: center;">Sheer Hydration Broad Spectrum SPF 40 Hydratante transparente FPS 40 à large spectre</p> <p style="text-align: center;">MOISTURIZING SUNSCREEN LOTION LOTION SOLAIRE HYDRATANTE</p> <p style="text-align: center;">UNTINTED / NON TEINTÉ</p> <p style="text-align: center;">NPN 80064932</p> <p style="text-align: center;">236 mL / 8 fl oz e</p>	<p>Drug Facts</p> <table border="1"> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> <tr> <td>Titanium Dioxide 7%.....</td> <td>Sunscreen</td> </tr> <tr> <td>Zinc Oxide 6.28 %.....</td> <td>Sunscreen</td> </tr> </table> <p>Use ■ helps prevent sunburn</p> <p>Warnings ■ For external use only.</p> <p>When using this product ■ do not use on damaged or broken skin ■ keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if you develop severe irritation, burning or itching of the skin, hives, swelling of eyes and mouth, blistering or difficulty breathing</p> <p>Keep out of reach of children. If swallowed, call a Poison Control Centre or get medical help right away.</p> <p>Directions ■ apply liberally/generously (and evenly) 15 minutes before sun exposure ■ reapply at least every 2 hours ■ for use on children less than 6 months of age, consult a health care practitioner ■ Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. 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ALUMIER MD SHEER HYDRATION			
titanium dioxide, zinc oxide lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69473-006
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	62.8 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALUMINUM MONOSTEARATE (UNII: P9BC99461E)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0K00R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ACACIA (UNII: 5C5403N26O)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDROXYETHYL BEHENAMIDOPROPYL DIMONIUM CHLORIDE (UNII: 9CO8OUL4TH)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLUTATHIONE (UNII: GAN16C9B8O)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: OR822556M5)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
C20-40 PARETH-10 (UNII: TE3MZI4V3F)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERIN (UNII: PDC6A3C0OX)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
RESVERATROL (UNII: Q369O8926L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69473-006-01	1 in 1 CARTON	07/01/2019	
1		236 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69473-006-02	1 in 1 CARTON	07/01/2019	06/30/2025
2		60 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:69473-006-03	8 mL in 1 TUBE; Type 0: Not a Combination Product	07/01/2019	02/28/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/01/2019	

Labeler - Alumier Labs (079603173)

Revised: 12/2024

Alumier Labs