

## **ALUMIER MD SHEER HYDRATION- titanium dioxide, zinc oxide lotion**

### **Alumier Labs**

*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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## **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, Polyquatemium-67, Disodium EDTA, Ethylhexylglycerin, Phenoxyethanol.

### **Company Information**

#### **Alumier MD**

#### **ALUMIER EUROPE LTD.**

5 ST. FREDERICK STREET  
VALLETTA VLT 1470, 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  
FRAMINGHAM, MA 01701

MANUFACTURED IN CANADA UNDER  
LICENSE FROM ALUMIER EUROPE LTD.

# Product Packaging - 236 mL

## Alumier MD

### Sheer Hydration

Broad Spectrum SPF 40

MOISTURIZING SUNSCREEN LOTION

UNTINTED

NPN 80064932

236 mL / 8 fl oz

<p><b>Alumier<sup>®</sup></b> ALUMIER EUROPE LTD. 5 ST. FREDERICK STREET VALLETTA VLT 1470, MALTA <a href="http://WWW.ALUMIERMD.COM">WWW.ALUMIERMD.COM</a> EUROPE • UNITED STATES • CANADA UNITED KINGDOM DISTRIBUTED IN CANADA BY / DISTRIBUÉ AU CANADA PAR : ALUMIER LABS INC., 436 LINSTONE CRESCENT TORONTO, ON, M3J 2S4 DISTRIBUTED IN THE USA BY / DISTRIBUÉ AUX ÉTATS-UNIS PAR : 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 OBTENUE PAR ALUMIER EUROPE LTD.</p>	<p><b>Notice</b></p> <table border="1"><thead><tr><th>Ingrédients actifs</th><th>Utilisation</th></tr></thead><tbody><tr><td>Dioxyde de titane 7 %</td><td>Crème solaire</td></tr><tr><td>Oxyde de zinc 6,28 %</td><td>Crème solaire</td></tr></tbody></table> <p><b>Usage</b> ■ protège contre les coups de soleil</p> <p><b>Avertissements</b> ■ Usage externe uniquement.</p> <p><b>Quand on utilise ce produit</b> ■ 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><b>Arrêtez l'utilisation et demandez à un docteur</b> 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><b>Garder hors de portée des enfants.</b> En cas d'ingestion, contacter un centre antipoison ou appeler un médecin immédiatement.</p> <p><b>Conseils d'utilisation</b> ■ 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><b>Autres Information</b> ■ 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>	Ingrédients actifs	Utilisation	Dioxyde de titane 7 %	Crème solaire	Oxyde de zinc 6,28 %	Crème solaire	<p><b>Alumier<sup>MD</sup></b></p> <p><b>Sheer Hydration</b> Broad Spectrum SPF 40 Hydratante transparente FPS 40 à large spectre</p> <p>MOISTURIZING SUNSCREEN LOTION LOTION SOLAIRE HYDRATANTE</p> <p>UNTINTED / NON TEINTÉ</p> <p>NPN 80064932</p> <p>236 mL / 8 fl oz e</p>	<p><b>Drug Facts</b></p> <table border="1"><thead><tr><th>Active Ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Titanium Dioxide 7%</td><td>Sunscreen</td></tr><tr><td>Zinc Oxide 6.28 %</td><td>Sunscreen</td></tr></tbody></table> <p><b>Use</b> ■ helps prevent sunburn</p> <p><b>Warnings</b> ■ For external use only.</p> <p><b>When using this product</b> ■ do not use on damaged or broken skin ■ keep out of eyes. Rinse with water to remove.</p> <p><b>Stop use and ask a doctor</b> if you develop severe irritation, burning or itching of the skin, hives, swelling of eyes and mouth, blistering or difficulty breathing</p> <p><b>Keep out of reach of children.</b> If swallowed, call a Poison Control Centre or get medical help right away.</p> <p><b>Directions</b> ■ 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</p> <p><b>Other Information</b> ■ 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, Frammingham, MA 01701</p> <p><b>Inactive Ingredients/Ingrédients inactifs</b> 1911023 - Water/Aqua/Eau, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Propenediol, Butyloctyl Salicylate, Cetearyl Alcohol, Aluminium Stearate, Glycerin, Glycerol Stearate, PEG-100 Stearate, Lecithin (Syn. Phosphatidylcholine), Vitis Vinifera Seed Extract, Resveratrol, Glutathione, Tocopherol Acetate, Magnesium Ascorbyl Phosphate, Acacia Senegal Gum, Synthetic Wax, Polyhydroxysteric Acid, Ceteareth-20, Alumina, Microcrystalline Cellulose Gum, C20-40 Pareth-10, Hydroxyethyl Behenamidopropyl Dimonium Chloride, Polyquaternium-67, Disodium EDTA, Ethylhexylglycerin, Phenoxethanol.</p>	Active Ingredients	Purpose	Titanium Dioxide 7%	Sunscreen	Zinc Oxide 6.28 %	Sunscreen
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## ALUMIER MD SHEER HYDRATION

titanium dioxide, zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69473-006
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	62.8 mg in 1 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	70 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>ALUMINUM MONOSTEARATE</b> (UNII: P9BC99461E)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>HYDROXYETHYL BEHENAMIDOPROPYL DIMONIUM CHLORIDE</b> (UNII: 9CO8OUL4TH)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>GLUTATHIONE</b> (UNII: GAN16C9B8O)	
<b>MAGNESIUM ASCORBYL PHOSPHATE</b> (UNII: 0R822556M5)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>C20-40 PARETH-10</b> (UNII: TE3MZI4V3F)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>VITIS VINIFERA SEED</b> (UNII: C34U15ICXA)	
<b>RESVERATROL</b> (UNII: Q369O8926L)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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	
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	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/01/2019	

**Labeler** - Alumier Labs (079603173)

Revised: 3/2022

Alumier Labs