

ALUMIER MD HYDRASMOOTH NON-COMEDOGENIC MOISTURIZER- salicylic acid cream

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.

Alumier MD HydraSmooth Non-Comedogenic Moisturizer

Drug Facts

Active Ingredient

Salicylic Acid 1.0%

Purpose

Acne treatment

Use

- for the treatment of acne

Warnings

- **For external use only.**

When using this product

- avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- skin irritation and dryness is more likely to occur if you use another topical acne product at the same time. If irritation occurs, only use one topical acne product at a time.

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.

- for more severe cases, and/or if improvement is not apparent within 6-8 weeks, consult a health care professional.

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

Directions

- cleanse skin thoroughly before applying the product
- cover the entire affected area with a thin layer one to three times daily or as directed by your health care practitioner
- if dryness or peeling occurs, reduce application to once a day or every other day

For New Users

- apply product to a small area once a day for three days to test if you are sensitive to this product
- if no discomfort occurs, cover the entire affected area with a thin layer
- start with one application daily, then gradually increase to two to three times daily, if needed
- if dryness or peeling occurs, reduce application to once a day or every other day.

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, Caprylyl Methicone, Propanediol, Dimethicone, Caprylic/Capric Triglyceride, Butylene Glycol, Glycerin, Potassium Cetyl Phosphate, Cetearyl Alcohol, Cocamidopropyl Dimethylamine, Sucrose Stearate, Glyceryl Stearate, Ammonium Acryloyldimethyltaurate/VP Copolymer, Aloe Barbadosensis Leaf Juice, Hinokitiol, Sea Whip Extract, Boswellia Serrata Gum Extract, Honey Extract (Extrait de Miel), Oryza Sativa (Rice) Bran Extract, Resveratrol, Allantoin, Oligopeptide-10, Spiraea Ulmaria Extract, Tocopheryl Acetate, Sodium Hyaluronate, Polysilicone-11, Polymethyl Methacrylate, Adipic Acid/Diglycol Crosspolymer, Tricaprylin, Caprylyl Glycol, Xanthan Gum, Caprylic Acid, Caprylic/Capric Triglyceride, Sorbitan Stearate, Sodium Hydroxide, Disodium EDTA, Xylitol, Citric Acid, Ethylhexylglycerin.

Company Information**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

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LICENSE FROM ALUMIER EUROPE LTD.

Product Packaging**Alumier MD****HydraSmooth**

Non-Comedogenic Moisturizer

ACNE TREATMENT

CREAM WITH

1% SALICYLIC ACID

NPN: 80063863

50 mL/1.7 fl oz

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, Framingham, MA 01701

Alumier

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Notice

Ingrédient actif Utilisation
Acide salicylique 1,0 %... Traitement de l'acné

Usage ■ pour le traitement de l'acné

Avertissements ■ Usage externe uniquement.

Quand on utilise ce produit
■ éviter le contact avec les yeux ; en cas de contact, rincer abondamment à l'eau
■ une irritation cutanée et une sécheresse sont plus susceptibles de se produire si vous utilisez un autre produit topique contre l'acné simultanément. En cas d'irritation, utilisez un seul produit topique contre l'acné à la fois.

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.

■ pour les cas plus graves, et/ou si une amélioration n'est pas constatée dans les 6 à 8 semaines, consulter un professionnel de santé

Garder hors de portée des enfants.
En cas d'ingestion, obtenir de l'aide médicale ou contacter un centre antipoison immédiatement.

Conseils D'Utilisation ■ nettoyer soigneusement la peau avant d'appliquer le produit. ■ couvrir une à trois fois par jour toute la zone touchée avec une fine couche ou selon les recommandations de votre professionnel de la santé ■ en cas de sécheresse ou de desquamation de la peau, réduire l'application à une fois par jour ou à tous les deux jours. **Pour les nouveaux utilisateurs** ■ appliquer le produit sur une petite zone une fois par jour pendant trois jours afin de tester votre sensibilité au produit. ■ si aucun inconfort ne survient, couvrir la zone affectée avec une fine couche de produit. ■ commencer par une application quotidienne, puis augmenter progressivement à deux ou trois fois par jour si nécessaire. ■ en cas de sécheresse ou de desquamation de la peau, réduire l'application à une fois par jour ou à tous les deux jours



HydraSmooth

Non-Comedogenic
Moisturizer
Soin hydratant
non comédogène

ACNE TREATMENT
CREAM WITH
1% SALICYLIC ACID
CRÈME TRAITEMENT
L'ACNÉ AVEC ACIDE
SALICYLIQUE À 1 %

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Inactive Ingredients/Ingrédients inactifs
1801142-2 - Water/Aqua/Eau, Caprylyl Methicone, Propanediol, Dimethicone, Caprylic/Capric Triglyceride, Butylene Glycol, Glycerin, Potassium Cetyl Phosphate, Cetearyl Alcohol, Cocamidopropyl Dimethylamine, Sucrose Stearate, Glyceryl Stearate, Ammonium Acryloyldimethylsulfate/VP Copolymer, Aloe Barbadosensis Leaf Juice, Hinokitiol, Sea Whip Extract, Boswellia Serrata Gum Extract, Honey Extract (Extrait de Miel), Onza Sativa (Fice) Bran Extract, Resveratrol, Allantoin, Oligopeptide-10, Spiraea Ulmaria Extract, Tocopherol Acetate, Sodium Hyaluronate, Poly silicone-11, Polymethyl Methacrylate, Adipic Acid/Diglycol Crosspolymer, Tricaprylin, Caprylyl Glycol, Xanthan Gum, Caprylic Acid, Caprylic/Capric Triglyceride, Sorbitan Stearate, Sodium Hydroxide, Disodium EDTA, Xylitol, Citric Acid, Ethylhexylglycerin.

ALUMIER MD HYDRASMOOTH NON-COMEDOGENIC MOISTURIZER

salicylic acid cream

Product Information

Product Type HUMAN OTC DRUG

Item Code (Source)

NDC:69473-003

Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
ADIPIC ACID/DIGLYCOL CROSSPOLYMER (20000 MPA.S) (UNII: R9TPS68K19)	
CAPRYLIC ACID (UNII: OBL58JN025)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
PROPANEDIOL (UNII: 5965N8W85T)	
SUCROSE STEARATE (UNII: 274KW0O50M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
WATER (UNII: 059QF0KO0R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
COCAMIDOPROPYL DIMETHYLAMINE (UNII: L36BM7DG2T)	
AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
RESVERATROL (UNII: Q369O8926L)	
ALLANTOIN (UNII: 344S277G0Z)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
.BETA.-THUJAPLICIN (UNII: U5335D6EBI)	
HONEY (UNII: Y9H1V576FH)	
RICE BRAN (UNII: R60QEP13IC)	
OLIGOPEPTIDE-10 (UNII: Q46328TRNK)	
FILIPENDULA ULMARIA WHOLE (UNII: 3LH0M209LN)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TRICAPRYLIN (UNII: 6P92858988)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XYLITOL (UNII: VCQ006KQ1E)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:69473-003-01	1 in 1 CARTON	07/01/2019	
1		50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	07/01/2019	

Labeler - Alumier Labs (079603173)

Revised: 5/2019

Alumier Labs