

ALUMIER MD ACNE BALANCING SERUM- 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 Acne Balancing Serum

Drug Facts

Active ingredient

Salicylic Acid 2.0%

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, get medical help or contact a Poison Control Centre 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 a 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, Dimethyl Isosorbide, Propanediol, Niacinamide, Glyceryl Caprate, Hinokitiol, Sea Whip Extract, Oryza Sativa (Rice) Bran Extract, Boswellia Serrata Gum Extract, Aloe Barbadensis Leaf Juice, Caprylic Acid, Caprylyl Glycol, Sodium Hyaluronate, Glycerin, Resveratrol, Oligopeptide-10, Honey Extract (Extrait de Miel), Allantoin, Ammonium Acryloyldimethyltaurate/VP Copolymer, Allyl Methacrylates Crosspolymer, Xanthan Gum, Cetyl Hydroxyethylcellulose, Pentylene Glycol, Disodium EDTA, Polymethyl Methacrylate, Tricaprylin, Sodium Hydroxide, Xylitol, Ethylhexylglycerin.

Company Information**ALUMIER EUROPE LTD.**

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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**Alumier MD****Acne Balancing Serum**

ACNE TREATMENT

WITH 2% SALICYLIC ACID

NPN: 80063862

30 mL/1 fl oz

Autres informations

- 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

Notice

Ingrédient actif Utilisation
Acide salicylique 2.0 %.....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



Acne Balancing Serum
Sérum d'équilibrage anti-acné

ACNE TREATMENT WITH 2% SALICYLIC ACID
TRAITEMENT DE L'ACNÉ AVEC 2 % D'ACIDE SALICYLIQUE

NPN: 80063862

30 mL/1 fl oz e

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ALUMIER MD ACNE BALANCING SERUM

salicylic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69473-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

CAPRYLIC ACID (UNII: OBL58JN025)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
RESVERATROL (UNII: Q369O8926L)
XANTHAN GUM (UNII: TTV12P4NEE)
EDETATE DISODIUM (UNII: 7FLD91C86K)
TRICAPRYLIN (UNII: 6P92858988)
XYLITOL (UNII: VCQ006KQ1E)
WATER (UNII: 059QF0KO0R)
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)
PROPANEDIOL (UNII: 5965N8W85T)
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
OLIGOPEPTIDE-10 (UNII: Q46328TRNK)
HONEY (UNII: Y9H1V576FH)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
NIACINAMIDE (UNII: 25X51I8RD4)
GLYCERYL CAPRATE (UNII: 197M6VFC1W)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GLYCERIN (UNII: PDC6A3C0OX)
AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER (UNII: W59H9296ZG)
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)
RICE BRAN (UNII: R60QEP13IC)
.BETA.-THUJAPLICIN (UNII: U5335D6EBI)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69473-002-01	1 in 1 CARTON	07/01/2019	
1		30 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)