

## **ALUMIER MD POST PROCEDURE KIT- titanium dioxide, zinc oxide**

### **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 Post Procedure Kit**

#### **Drug Facts - Sheer Hydration**

##### **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., 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. Phosphatidycholine), Vitis Vinifera Seed Extract, Resveratrol, Glutathione, Tocopheryl Acetate, Magnesium Ascorbyl Phosphate, Acacia Senegal Gum, Synthetic Wax, Polyhydroxyesteric 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.

### **Company Information**

#### **Alumier MD**

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

5 ST. FREDERICK STREET

VALLETTA VLT 1470, MALTA

#### **WWW.ALUMIERMD.COM**

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### **Product Packaging**

**You have just received an AlumierMD Skin Treatment.** This post-care kit has been created to care for your skin following a chemical peel or professional treatment. In order to obtain the maximum results and avoid complications, please follow the post peel regimen and use only the following three AlumierMD products for 5 to 7 days. Discontinue use if any products cause burning on the skin and contact your skin care provider.

**AM Protocol**  
 Step 1: SensiCalm  
 Step 2: Recovery Balm  
 Step 3: Sheer Hydration Broad Spectrum SPF 40

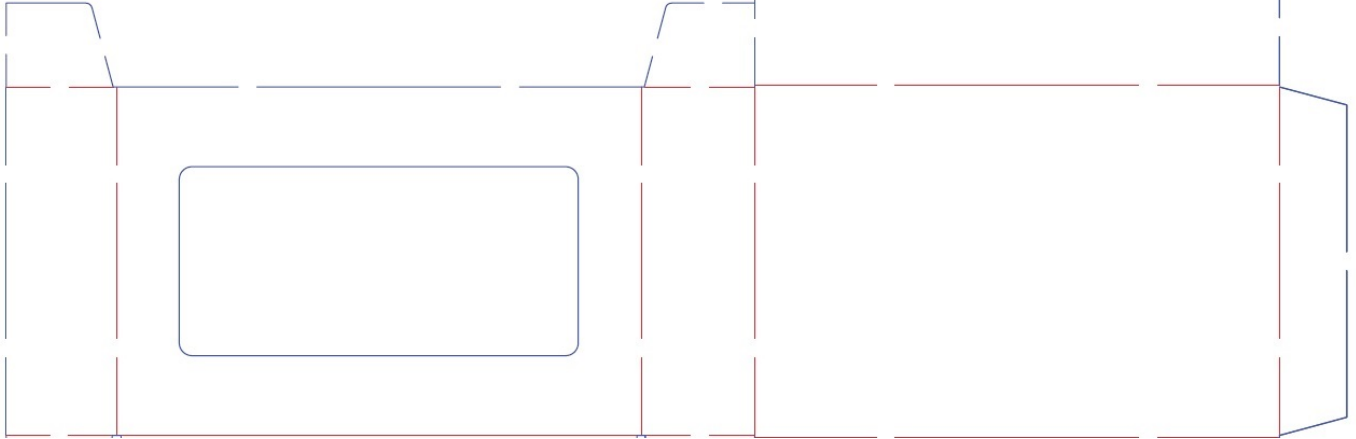
**PM Protocol**  
 Step 1: SensiCalm  
 Step 2: Recovery Balm

**Vous venez de bénéficier d'un traitement dermatologique AlumierMD.** Ce kit post-traitement a été créé pour prendre soin de votre peau après un peeling chimique ou un traitement professionnel. Pour obtenir les meilleurs résultats et éviter des complications, veuillez suivre le protocole post-peeling et utiliser uniquement les trois produits AlumierMD suivants pendant 5 à 7 jours. Cessez l'utilisation si l'un des produits vous brûle la peau et contactez immédiatement votre médecin.

**Protocole du matin**  
 Étape 1: SensiCalm  
 Étape 2: Baume Recovery  
 Étape 3: Crème hydratante transparente FPS 40 à large spectre

**Protocole du soir**  
 Étape 1: SensiCalm  
 Étape 2: Baume Recovery

Please refer to your Post Procedure Care Instructions for detailed instructions on how to care for your skin post peel.  
 Reportez-vous à vos instructions de post-traitement pour des instructions détaillées sur la façon de prendre soin de votre peau de peau.



INSTRUCTIONS POST-TREATMENT  
 INSTRUCCIONES POSTERIORES AL PROCEDIMIENTO

香港總經銷商

INSERT NO.: A8011-6



Alumier®  
 Alumier Europe LTD  
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 EUROPE • UNITED STATES • CANADA  
 UNITED KINGDOM  
 MANUFACTURED IN CANADA UNDER  
 LICENSES BY ALUMIER EUROPE LTD  
 ENJOYED BY CANADA SOUS LICENCE  
 FABRIQUE PAR ALUMIER EUROPE LTD  
 OCTOBER 2018

**POST PROCEDURE KIT:**

**3 STEPS. 5 DAYS TO GLOWING SKIN.**

YOU HAVE JUST RECEIVED AN ALUMIERMD SKIN TREATMENT. THIS POST-CARE KIT HAS BEEN CREATED TO CARE FOR YOUR SKIN FOLLOWING A CHEMICAL PEEL OR PROFESSIONAL TREATMENT. IN ORDER TO OBTAIN THE MAXIMUM RESULTS AND AVOID COMPLICATIONS, PLEASE FOLLOW THE POST PEEL REGIMEN AND USE ONLY THE FOLLOWING THREE ALUMIERMD PRODUCTS FOR 5 TO 7 DAYS. DISCONTINUE USE IF ANY PRODUCTS CAUSE BURNING ON THE SKIN AND CONTACT YOUR SKIN CARE PROVIDER.

**AM PROTOCOL**

- STEP 1: SENSCALM CLEANSER
- STEP 2: RECOVERY BALM
- STEP 3: SHEER HYDRATION BROAD SPECTRUM SPF 40

**PM PROTOCOL**

- STEP 1: SENSCALM CLEANSER
- STEP 2: RECOVERY BALM

PLEASE REFER TO YOUR POST PROCEDURE CARE INSTRUCTIONS FOR DETAILED INSTRUCTIONS ON HOW TO CARE FOR YOUR SKIN POST PEEL.

YOUR POST-CARE KIT CONTAINS THE FOLLOWING ALUMIERMD SKIN CARE PRODUCTS:

**SENSICALM**

SENSICALM CLEANSER IS A SMOOTH, HYDRATING CLEANSER THAT DELICATELY REMOVES IMPURITIES AND EXCESS OIL WHILE CALMING SKIN. YUCCA ROOT EXTRACT IS A GENTLE NATURAL CLEANSER; NIACINAMIDE, CERAMIDES, VITAMIN E AND SUNFLOWER SEED OIL MOISTURISE, LEAVING SKIN SMOOTH, SOFT AND INTENSELY HYDRATED. ALOE SOOTHES SKIN AND CALMS REDNESS.

**DIRECTIONS FOR USE:** TWICE A DAY, USE A SMALL AMOUNT WITH WATER AND MASSAGE OVER YOUR FACE AND NECK. RINSE THOROUGHLY AND PAT DRY.

**RECOVERY BALM**

RECOVERY BALM IS SPECIFICALLY FORMULATED FOR POST-PROCEDURE RECOVERY. PACKED WITH SOOTHING ANTIOXIDANT INGREDIENTS, THIS MOISTURISER CALMS SKIN, HINOKITOL AND SEA WHIP RELIEVE REDNESS. ALOE, HONEY AND BOSWELLIA SOOTHE AND COPPER PPTOR REPAIRS THE LOOK OF SKIN.

**DIRECTIONS FOR USE:** APPLY TO FACE AND NECK POST-TREATMENT. USE UP TO THREE TIMES PER DAY FOR A MAXIMUM OF 5 DAYS POST PEEL.

**SHEER HYDRATION BROAD SPECTRUM SPF 40**

A SLIMY AND SHEER PHYSICAL SUNSCREEN THAT PROVIDES POWERFUL PROTECTION AGAINST HARMFUL UVA AND UVB RAYS. IT USES A COMBINATION OF ZINC OXIDE AND TITANIUM DIOXIDE, WHILE MOISTURISING WITH VITAMIN E. THIS FORMULA IS ALSO PACKED WITH FREE-RADICAL-QUENCHING ANTIOXIDANTS, INCLUDING A STABLE VITAMIN C, VITAMIN E, RESVERATROL, GRAPE SEED EXTRACT AND GLUTATHIONE, TO PROTECT SKIN FROM UV DAMAGE.

**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

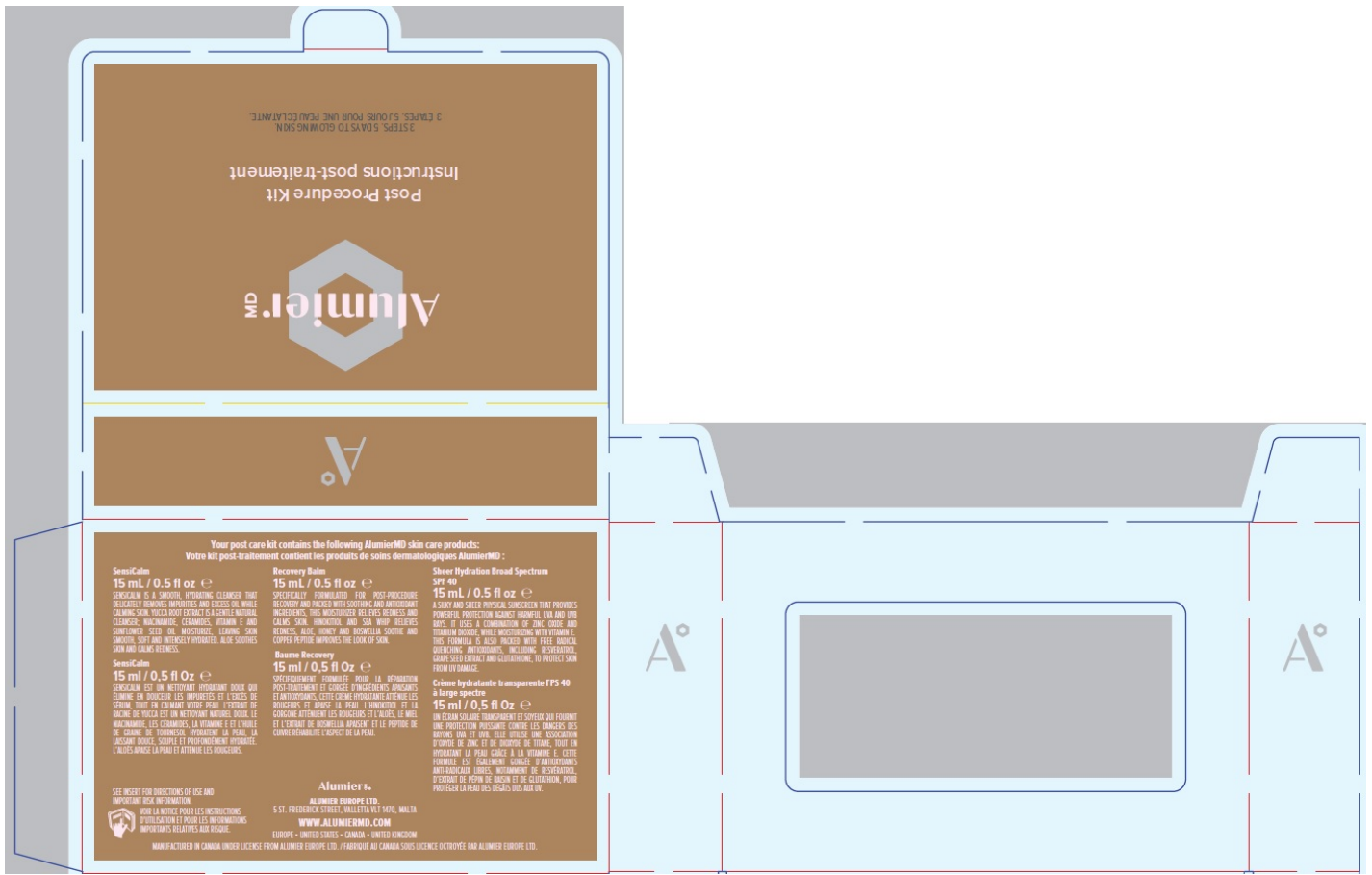
■ for use on children less than 6 months of age, consult a health care practitioner

■ **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. to 4 p.m. - wear long-sleeved shirts, pants, hats and

sunglasses  
 ■ Use a water resistant sunscreen if swimming or sweating

**Other Information**  
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**Inactive Ingredients/Ingredients Inactive** 1911023 - Water/Aqua/Eau, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Propylene Glycol, Butylacetyl Salicylate, Cetylal Alcohol, Aluminum 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, Polyhydroxyethyl Acrylate, Cellulose 20, Alumina, Microcrystalline Cellulose, Trihydroxycapryllate, Xanthan Gum, Cellulose Gum, Cetyl-40 Pareth-10, Hydroxyethyl Behenylsulfonate, Dimonium Chloride, Polyquaternium-67, Disodium EDTA, Ethylhexylglycerin, Phenoxethanol.



## ALUMIER MD POST PROCEDURE KIT

titanium dioxide, zinc oxide kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69473-012
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69473-012-01	1 in 1 CARTON; Type 0; Not a Combination Product	11/30/2020	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	15 mL
Part 2	1 TUBE	15 mL
Part 3	1 TUBE	15 mL

Part 1 of 3

**ALUMIER MD SHEER HYDRATION**

titanium dioxide, zinc oxide lotion

### Product Information

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
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ACACIA (UNII: 5C5403N26O)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
HYDROXYETHYL BEHENAMIDOPROPYL DIMONIUM CHLORIDE (UNII: 9CO8OUL4TH)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
C20-40 PARETH-10 (UNII: TE3MZI4V3F)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERIN (UNII: PDC6A3C0OX)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
ALUMINUM MONOSTEARATE (UNII: P9BC99461E)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PROPANEDIOL (UNII: 5965N8WB5T)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
GLUTATHIONE (UNII: GAN16C9B8O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
RESVERATROL (UNII: Q369O8926L)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

### Packaging

#	Item	Package Description	Marketing Start	Marketing End
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#	Code	Package Description	Date	Date
1		15 mL 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	11/30/2020	

## Part 2 of 3

### ALUMIER MD SENSICALM

cleansing (cold creams, cleansing lotions, liquids, and pads) cream

## Product Information

**Route of Administration** TOPICAL

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
INGR	<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
INGR	<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
INGR	<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
INGR	<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
INGR	<b>P-ANISIC ACID</b> (UNII: 4SB6Y7DMM3)	
INGR	<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
INGR	<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
INGR	<b>CAPRYLYL/CAPRYL OLIGOGLUCOSIDE</b> (UNII: E00JL9G9K0)	
INGR	<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
INGR	<b>CAPRYLIC ACID</b> (UNII: OBL58JN025)	
INGR	<b>4-TERPINEOL, (+/-)-</b> (UNII: L65MV77ZG6)	
INGR	<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
INGR	<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
INGR	<b>COCAMIDOPROPYL HYDROXYSULTAINE</b> (UNII: 62V75NI93W)	
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
INGR	<b>SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW)</b> (UNII: 1DXE3F3OZX)	
INGR	<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
INGR	<b>YUCCA SCHIDIGERA ROOT</b> (UNII: E2H9ET15AT)	
INGR	<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
INGR	<b>LINALYL ACETATE</b> (UNII: 5K47SSQ51G)	

INGR	<b>.BETA.-OCIMENE, (3Z)-</b> (UNII: 472UVP4R7T)	
INGR	<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
INGR	<b>DISODIUM COCOYL GLUTAMATE</b> (UNII: MBK0CP8F5A)	
INGR	<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
INGR	<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
INGR	<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
INGR	<b>CERAMIDE NG</b> (UNII: C04977SRJ5)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		15 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		07/01/2019	

### Part 3 of 3

## ALUMIER MD RECOVERY BALM

face and neck (excluding shaving preparations) cream

### Product Information

**Route of Administration** TOPICAL

### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
INGR	<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
INGR	<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
INGR	<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
INGR	<b>PREZATIDE COPPER</b> (UNII: 6BJQ43T1I9)	
INGR	<b>INDIAN FRANKINCENSE</b> (UNII: 4PW41QCO2M)	
INGR	<b>HONEY</b> (UNII: Y9H1V576FH)	
INGR	<b>CHAMAEMELUM NOBILE FLOWER</b> (UNII: O2T154T6OG)	
INGR	<b>PATCHOULI OIL</b> (UNII: F3IN55X5PO)	
INGR	<b>ROSEMARY</b> (UNII: IJ67X351P9)	
INGR	<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
INGR	<b>TRICAPRYLIN</b> (UNII: 6P92858988)	

INGR	<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
INGR	<b>SODIUM METHYL STEAROYL TAURATE</b> (UNII: JFM219LJ55)	
INGR	<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
INGR	<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
INGR	<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
INGR	<b>CRANBERRY</b> (UNII: 0MVO31Q3QS)	
INGR	<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
INGR	<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
INGR	<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
INGR	<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
INGR	<b>.BETA.-THUJAPLICIN</b> (UNII: U5335D6EBI)	
INGR	<b>RESVERATROL</b> (UNII: Q369O8926L)	
INGR	<b>LAVANDULA ANGUSTIFOLIA FLOWERING TOP</b> (UNII: 9YT4B71U8P)	
INGR	<b>ASPALATHUS LINEARIS LEAF</b> (UNII: H7UGK1GJCU)	
INGR	<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: S546YLW6E6)	
INGR	<b>MENTHA SPICATA</b> (UNII: O2H83I4PUN)	
INGR	<b>SQUALANE</b> (UNII: GW89575KF9)	
INGR	<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
INGR	<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
INGR	<b>APPLE</b> (UNII: B423VGH5S9)	
INGR	<b>PSEUDOPTEROGORGIA ELISABETHAE</b> (UNII: UDY3H1OUX5)	
INGR	<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
INGR	<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
INGR	<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
INGR	<b>CAPRYLIC ACID</b> (UNII: OBL58JN025)	

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1		15 mL in 1 TUBE; Type 0: Not a Combination Product		

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Cosmetic		07/01/2019	

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OTC monograph not final	part352	11/30/2020	

**Labeler** - Alumier Labs (079603173)



