

**PRO-TECT EVERYDAY SUNSCREEN SPF 15- octinoxate, octisalate, padimate o lotion
A-Cute Derm, Incorporated**

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.

DRUG FACTS

Pro-Tect® SPF 15+ Sunscreen Broad-Spectrum UVA/UVB Protection & Moisturizing Lotion

Active Ingredients

Octinoxate.....	7.5%
Oxybenzone.....	2.0%
Padimate O.....	5.0%

Purpose

Sunscreen

Uses

•Pro-Tect® SPF 15+ Broad-Spectrum UVA & UVB protection. •Helps prevent sunburn. •Retains a SPF of 15+ after 80 minutes of activity in water of perspiring. •Provides high protection against sunburn and tanning. •For skin highly sensitive to sunburn.

Warnings

•External use only. •When using this product, keep out of eyes. •Rinse with water to remove. •Stop use and ask a doctor if rash or irritation develops and lasts. •Do not use if sensitive to any of the ingredients of their related compounds.

KEEP OUT OF REACH OF CHILDREN

Directions

•Apply liberally and evenly on all exposed areas 20-30 minutes before exposure to the sun and as needed.
•Children under 6 months of age: ask a doctor.

Inactive ingredients

Aloe Vera Leaf, Benzyl Alcohol, Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked), Cetyl Alcohol, Diazolidinyl Urea, Diethanolamine Cetyl Phosphate, dl-Alpha Tocopheryl Acetate, Iodopropynyl Butylcarbamate, Trolamine, Water.

Other Information

•Daily usage of Pro-Tect SPF15+ may help reduce the chance of premature aging of the skin due to overexposure to the sun. •This product provides more than 15 times your natural protection against sunburn. •Very Water Resistant UVA & UVB Broad-Spectrum Protection. •This product may stain light colored fabrics if washed with bleach. Wash clothing without bleach to remove safely.

Questions or Comments

Bio-Medical & Pharm. Mfg. Corp.

4311 South Dr.

Houston, TX 77053-4820

281-835-8051

M-F 8AM-5PM

www.bio-medicalmanufacturing.com

Principal Display Panel

<p>Inactive Ingredients Aloe Vera Leaf, Benzyl Alcohol, Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked), Cetyl Alcohol, Diazolidinyl Urea, Diethanolamine Cetyl Phosphate, dl-Alpha Tocopheryl Acetate, Iodopropynyl Butylcarbamate, Triamine, Water.</p>	 <p>A-CUTE DERM medical skincare</p>	<p>Drug Facts Pro-Tect® SPF 15 Sunscreen Broad-Spectrum UVA/UVB Protection & Moisturizing Lotion.</p>											
<p>Other Information •Daily usage of Pro-Tect® SPF 15 may help reduce the chance of premature aging of the skin due to overexposure to the sun. •This product provides more than 15 times your natural protection against sunburn. •Very Water Resistant UVA & UVB Broad-Spectrum Protection.</p>		<table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>%</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Octinoxate.....</td> <td>7.5...</td> <td>Sunscreen</td> </tr> <tr> <td>Padimate O.....</td> <td>5.0...</td> <td>Sunscreen</td> </tr> <tr> <td>Oxybenzone.....</td> <td>2.0...</td> <td>Sunscreen</td> </tr> </tbody> </table>	Active Ingredients	%	Purpose	Octinoxate.....	7.5...	Sunscreen	Padimate O.....	5.0...	Sunscreen	Oxybenzone.....	2.0...
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<p>Questions or Comments A-Cute Derm, Inc. 1810 Cravens Road Stafford, TX 77477 800.922.2883 M-F 8:30am-5:30pm info@a-cutederm.com www.a-cutederm.com</p>	<p>PRO-TECT® SPF 15 SUNSCREEN</p>	<p>Uses •Pro-Tect® SPF 15 Broad-Spectrum UVA & UVB protection. •Helps prevent sunburn. •Retains a SPF of 15 after 80 minutes of activity in water or perspiring. •Provides high protection against sunburn and tanning. •For skin highly sensitive to sunburn.</p>											
<p>Pro-Spectrum Process™ Broad-Spectrum UVA/UVB Sunscreen</p>		<p>Warnings •External use only. •When using this product, keep out of eyes. •Rinse with water to remove. •Stop use and ask a doctor if rash or irritation develops and lasts. •Do not use if sensitive to any of the ingredients or their related compounds.</p>											
<p>Greaseless & Very Water-Resistant Fortified with Aloe & Vitamin E Fragrance Free Non-Comedogenic NDC# 61619-868-35 5.0 GAL (18.9 kg)</p>		<p>KEEP OUT OF REACH OF CHILDREN Directions •Apply liberally and evenly on all exposed areas 20-30 minutes before exposure to the sun and as needed. •Children under 6 months of age: ask a doctor.</p>											
<p> Marketed by A-Cute Derm, Inc. Stafford, TX 77477 Item 86020 • V. 101315 Animal Cruelty Free • Made in U.S.A.</p>		 <p>7 54405 86020 1</p>											

Pro-Tect

SPF 15

Sunscreen

5.0 GAL (18.9 KG)

NDC:61619-868-35

PRO-TECT EVERYDAY SUNSCREEN SPF 15

octinoxate, octisalate, padimate o lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61619-868
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	20 mg in 1 g
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61619-868-35	18900 g in 1 CONTAINER; Type 0: Not a Combination Product	11/03/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/03/2015	

Labeler - A-Cute Derm, Incorporated (809845803)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(61619-868)