DERMELEVE- aluminum acetate cream Advanced Derm Solutions LLC

Active Ingredient

Aluminum acetate (0.2%)

Purpose

Astringent

Uses

- Insects Bites
- Minor Burn
- Athlete's foot
- Poison lvy
- Poison oak
- Poison sumac
- Rashes cause by soaps, detergents, cosmetic or jewelry

Warnings

- **■** For external use only.
- **Avoid**contact with eyes.
- **Do not apply**to open wounds.
- **STOP USE**and ask a physician if condition worsens or symptoms persist for more than seven days.
- Keep out of reach of children.

Directions

Adults and children two years of age and older, apply to affected area as needed or as directed by a physician. Consult a physician for children under the age of two.

Inactive ingredients

Caprylyc/Capric Triglyceride, Caprylyl Glycol, Ceramide NG, Cetearyl Alcohol, Dimethicone 100.

Disodium Edta, Emulsifying Wax NF, Glycerin, Glyceryl Stearate SE, Sodium Hyaluronate, Isopropyl Myristate Magnesium Aluminum Silicate Type IA, Phenoxyethanol, Polyacrylate Crosspolymer-6, Shea Butter, Strontium Nitrate, Tetrahexyldecyl Ascorbate, Tocopherol, Water O-18, Xanthan Gum

Manufactured for Advanced Derm Solutions LLC

Oldsmar, FL 34677 | dermeleve.com

U.S. Patents: 5,716,625; 5,804,203; 6,139,850; 7,404,967

Product label



ADVANCED FORMULA

Relieves dry, itchy and irritated skin

Helps retain moisture in the skin

Aids skin barrier function

STEROID FREE

With SrX-38™

Feel the Difference

- Aluminum Acetate (0.2%)
- Strontium Mineral Salts
- Ceramides
- Hyaluronic Acid
- Shea Butter
- Vitamins C+E

SOUTHING CREAM

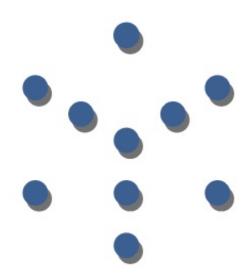
Made in USA

120g

DERMELEVE_®

For all skin types

Dermeleve® may be used topically for the temporary relief of minor skin irritations.



Store below 75°F / 24°C

SrX-38[™] is a trademark of Advanced Derm Solutions LLC



Dermeleve®

Dermeleve® is formulated for dry and itchy skin using the latest advancements in dermatological science.

DERMELEVE® ADVANCED

FORMULA Soothing Cream is a proprietary formula that delivers effective relief and moisturizes the skin.

SrX-38™

SrX-38™ is a proprietary formulation containing active drug and soothing cosmetic ingredients, including Aluminum Acetate, Strontium Mineral Salts, Hyaluronic Acid, Shea Butter, Ceramides, and Vitamins C+E that have been clinically proven to reduce irritation and itch while enhancing the natural skin barrier to lock in moisture and block external irritation.

Daily use of Dermeleve® ADVANCED FORMULA Soothing Cream can help reduce the irritation from extremely dry and itchy or eczema prone skin. Visible improvement in the skin's condition may be observed with regular use.

Advanced Derm Solutions LLC

Made in USA 120g



ADVANCED FORMULA

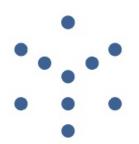
Relieves dry, itchy and irritated skin

Helps retain moisture in the skin
Aids skin barrier function

STEROID FREE

Contains

- Aluminum Acetate (0.2%)
- Strontium Mineral Salts
- Ceramides
- Hyaluronic Acid
- Shea Butter
- Vitamins C+E



SrX-38TM
Feel the Difference

SOOTHING CREAM

Made in USA

120g

DERMELEVE®

Drug Facts Active Ingredient

Purpose

Aluminum acetate (0.2%).....

Astringent

Uses

- Insect Bites
 Minor burn
 Athlete's Foot
- Poison Ivy
 Poison Oak
 Poison Sumac
- Rashes caused by soaps, detergents, cosmetics, or jewelry

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Directions

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Inactive Ingredients

Water, Strontium Nitrate, Isopropyl Myristate, Butyrospermum Parkii (shea) Butter, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Emulsifying Wax NF, Glycerin, Phenoxyethanol, Magnesium Aluminum Silicate, Glyceryl Stearate, Dimethicone, Polyacrylate

NDC# 81507-XXXXX

Crosspolymer-6, Xanthan Gum, Caprylyl Glycol, Sodium Hyaluronate, Disodium EDTA, Ceramide NG, Tocopherol (Vitamin E), Tetrahexyldecyl Ascorbate

Questions? Visit www.dermeleve.com

Manufactured for Advanced Derm Solutions LLC Oldsmar, FL 34677 | dermeleve.com

U.S. Patents: 5,716,625; 5,804,203; 6,139,850; 7,404,967



DERMELEVE

aluminum acetate cream

Product	Information	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81507-003

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM ACETATE (UNII: 80EHD8I43D) (ALUMINUM CATION - UNII:3XHB1D032B)	ALUMINUM ACETATE	0.2 g in 100 g

Inactive Ingredients

Ingredient Name Strength

CERAMIDE NG (UNII: C04977SRJ5)	
DIMETHICONE 100 (UNII: RO266O364U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MAGNESIUM ALUMINUM SILICATE TYPE IA (UNII: SUS08ZOA9S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SHEA BUTTER (UNII: K49155WL9Y)	
STRONTIUM NITRATE (UNII: BDG873AQZL)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER O-18 (UNII: 7QV8F8BYNJ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLAWAX POLYSORBATE (UNII: Q504PL8E0V)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:81507-003- 01	120 g in 1 TUBE; Type 0: Not a Combination Product	02/04/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	02/04/2022	

Labeler - Advanced Derm Solutions LLC (117840544)

Revised: 12/2023 Advanced Derm Solutions LLC