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 doctor 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 doctor. Consult a doctor for children under the age of two.

Inactive ingredients

Water, Strontium Nitrate, Isopropyl Myristate, Butyrospermum Parkii (shea) Butter, Caprylyc/Capric Triglyceride, Cetearyl Alcohol, Emulsifying Wax NF, Glycerin, Phenoxyethanol, Magnesium Aluminum Silicate, Glyceryl Stearate, Dimethicone, Polyacrylate Crosspolymer-6, Xanthan Gum, Caprylyl Glycol, Sodium Hyaluronate, Disodium EDTA, Ceramide NG, Tocopherol (Vitamin E), Tetrahexyldecyl Ascorbate

Manufactured for Advanced Derm Solutions LLC

Ocala, FL 34482 | dermeleve.com

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

Product label

Live Without Itch!



Steroid Free Itch Relief Cream



Active Ingredient

Purpose

Aluminum acetate (0.2%).

. Astringer

Uses

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

Water, Strontium Nitrate, Isopropyl Myristate, Butyrospermum Parkii (shea) Butter, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Emulsifying Wax NF, Glycerin, Phenoxyethenol, Magnesium Aluminum Silicate, Glyceryl Stearate, Dimethicone, Polyacrylate 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 Ocolo, FL 34482 | dermeleve.com U.S. Patents: 5,716,625; 5,804,203: 6,139,850; 7,404,967 NDC#





Relieves dry, itchy and irritated skin

Helps retain moisture in the skin Aids skin barrier function

STEROID FREE

Contains

- Aluminum Acetate
- Strontium Mineral Salts
- Ceramides
- · Hyaluronic Acid
- Shea Butter
- Vitamins C+E



SOOTHING CREAM

Made in USA

30g

TUBE FRONT

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 irritaiton 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

30g

BOX LEFT



Relieves dry, itchy and irritated skin

Helps retain moisture in the skin Aids skin barrier function

STEROID FREE

With SrX-38™



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

SOOTHING CREAM

Made in USA

30g

BOX FRONT



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



SOOTHING CREAM

Made in USA

80g



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



BOX RIGHT.



Active Ingredient

Purpose

Aluminum acetate (0.2%)....

Astringent

- Insect Bites Minor Bum Athlete's Foot Poison Ivy Poison Oak Poison Sumac

■ Rashes caused by soaps, detergents, cosmetics or jewelry

Warnings

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

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

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

Questions? Visit www.dermeleve.com

Manufactured for Advanced Derm Solutions LLC Ocala, FL 34472 | dermeleve.com U.S. Patents: 5,716,625; 5,804,203; 6,139,850; 7,404,967

NDC#



BOX BACK.

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
improvemenet in the skin's
condition may be observed
with regular use.

Advanced Derm Solutions LLC

Made in USA 60g



Active Ingredient

Purpose

Aluminum acetate (0.2%).....

Astringent

Uses

- Relieves minor skin irritations due to poison ivy
- Poison oak Poison sumac Insect bites
- Allergic itches Minor burn

Warnings

- For external use only.
- Avoid contact with eyes.
- Do not apply to open wounds.
- STOP USE and ask a doctor 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 doctor. Consult a doctor for children under the age of two.

Inactive Ingredients

Water, Strontium Nitrate, Isopropyl Myristate, Butyrospermum Parkii (shea) Butter, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Emulsifying Wax NF, Glycerin, Phencxyethanol, Magnesium Aluminum Silicate, Glyceryl Stearate, Dimethicone, Polyacrylate 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 Ocala, FL 34482 | dermeleve.com U.S. Patents; 5,716,625; 5,804,203; 6,139,850; 7,404,96 7

NDC# XXXXXXXX





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



BOX RIGHT



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



SOOTHING CREAM

Made in USA

60g

TUBE FRONT.



Warnings

- For external use only.
- Avoid contact with eyes.
- Do not apply to open wounds.
- STOP USE and ask a doctor 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 doctor. Consult a doctor for children under the age of two. NDC 81507-xxxx

To Order, visit www.dermeleve.com or call (877) 684-2299

Advanced Derm Solutions Oldsmar, FL Tel: +1 (877) 684-2299

www.dermeleve.com

NOT FOR INDIVIDUAL RETAIL SALE. To Be Sold in sets.

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 lewelry

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

Inactive Ingredients

Water, Strontium Nitrate, Isopropyl Myristate, Butyrospermum Parkii (shea) Butter, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Emulaifying Wax NF, Glycerin, Phenoxyethanol, Magnesium Aluminum Silicate, Glyceryl Stearate, Dimethicone, Polyacrylate Crosspolymer-6, Xanthan Gum, Caprylyl Glycol, Sodium Hyaluronate, Discdium EDTA, Ceramide NG, Tocopherol (Vitamin E), Tetrahexyldecyl Ascorbate

Questions? Visit www.dermeleve.com

Manufactured for Advanced Derm Solutions LLC Ocala, Ft. 34482 | dermeleve.com U.S. Patents: 5,716,625; 5,804,203; 6,139,850; 7,404,987



NDC



Active Ingredient

Purpose

Aluminum acetate (0.2%)...... Astringent

- relieves minor skin irritations due to poison ivy
- Poison oak Poison sumac Insect bites
- Athlete's foot Allergic itches Minor burn

Warnings

- For external use only.
- Avoid contact with eyes.
- Do not apply to open wounds.
- STOP USE and ask a doctor 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 doctor. Consult a doctor for children under the age of two.

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 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 Ocala, FL 34472 | dermeleve.com U.S. Patents: 5,716,625; 5,804,203; 6,139,850; 7,404,967

NDC# XXXXXXXX





Relieves dry, itchy and irritated skin

Helps retain moisture in the skin Aids skin barrier function

STEROID FREE

With SrX-38™



SOOTHING CREAM

Made in USA 60g

BOX FRONT

DERMELEVE

aluminum acetate cream

Product	Intorm	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81507-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Daala of

Ingredient Name	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)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYACRYLIC ACID (450000 MW) (UNII: KD3S7H73D3)	
HYALURONIC ACID (UNII: S270N0TRQY)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
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)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLAWAX POLYSORBATE (UNII: Q504PL8E0V)	
SHEA BUTTER (UNII: K49155WL9Y)	
STRONTIUM NITRATE (UNII: BDG873AQZL)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER O-18 (UNII: 7QV8F8BYNJ)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:81507-002- 01	30 g in 1 TUBE; Type 0: Not a Combination Product	06/05/2021		
NDC:81507-002- 02	60 g in 1 TUBE; Type 0: Not a Combination Product	06/05/2021		
NDC:81507-002- 03	3 g in 1 POUCH; Type 0: Not a Combination Product	06/05/2021	08/04/2022	
NDC:81507-002- 04	80 g in 1 TUBE; Type 0: Not a Combination Product	06/05/2021		
NDC:81507-002- 05	2 g in 1 POUCH; Type 0: Not a Combination Product	08/04/2022		
	NDC:81507-002- 01 NDC:81507-002- 02 NDC:81507-002- 03 NDC:81507-002- 04 NDC:81507-002-	NDC:81507-002- 01 NDC:81507-002- 02 NDC:81507-002- 03 g in 1 TUBE; Type 0: Not a Combination Product NDC:81507-002- 03 g in 1 POUCH; Type 0: Not a Combination Product NDC:81507-002- 04 NDC:81507-002- 04 NDC:81507-002- 04 NDC:81507-002- 04 NDC:81507-002- 04 NDC:81507-002- 04 NDC:81507-002- 05 NDC:81507-002- 06 NDC:81507-002- 07 NDC:81507-002- 08 NDC:81507-002- 09 NDC:815	Item Code Package Description Marketing Start Date NDC:81507-002- 01 30 g in 1 TUBE; Type 0: Not a Combination Product 06/05/2021 NDC:81507-002- 02 60 g in 1 TUBE; Type 0: Not a Combination Product 06/05/2021 NDC:81507-002- 03 3 g in 1 POUCH; Type 0: Not a Combination Product 06/05/2021 NDC:81507-002- 04 80 g in 1 TUBE; Type 0: Not a Combination Product 06/05/2021 NDC:81507-002- 04 2 g in 1 POUCH; Type 0: Not a Combination 08/04/2022	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M016	06/05/2021		

Labeler - Advanced Derm Solutions LLC (117840544)

Revised: 10/2024 Advanced Derm Solutions LLC