

DERMELEVE- pramoxine hydrochloride cream
Advanced Derm Solutions LLC

Active Ingredient

Pramoxine Hydrochloride (1%)

Purpose

External analgesic

Uses

For temporary relief of pain and itching associated with skin irritations, minor burns, sunburn, and rashes due to poison ivy, poison oak, or poison sumac

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.

Store at 20-25°C (68-77°F). Keep carton for full product information

Questions? Visit www.dermeleve.com or call +1 (877)-684-2299

Inactive ingredients

Ascorbyl Tetraispalmitate, Butyrospermum Parkii (shea) Butter, Caprylic/Capric Triglyceride, Caprylyl Glycol, Ceramide NG, Cetearyl Alcohol Dimethicone, Disodium EDTA, Glycerin, Glyceryl Stearate, Isopropyl Myristate, Magnesium Aluminum Silicate, Phenoxyethanol, Polyacrylate Crosspolymer-6, Polysorbate 60, Propylene Glycol, Sodium Hyaluronate, Strontium Nitrate, Tocopherol Acetate (Vitamin E), Water, Xanthan Gum

Dermeleve®

Drug Facts

Active Ingredient

Purpose

Pramoxine Hydrochloride (1%) External analgesic

Uses

- For temporary relief of pain and itching associated with skin irritations, minor burns, sunburn, and rashes due to poison ivy, poison oak, or poison sumac

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

Ascorbyl Tetraispalmitate, Butyrospermum Parkii (shea) Butter, Caprylic/ Capric Triglyceride, Caprylyl Glycol, Ceramide NG, Cetearyl Alcohol, Dimethicone, Disodium EDTA, Glycerin, Glyceryl Stearate, Isopropyl Myristate, Magnesium Aluminum Silicate, Phenoxyethanol, Polyacrylate Crosspolymer-6, Polysorbate 60, Propylene Glycol, Sodium Hyaluronate, Strontium Nitrate, Tocopherol Acetate (Vitamin E), Water, Xanthan Gum

Questions? Visit www.dermeleve.com
or call +1 (877) 684-2299

Manufactured for Advanced Derm Solutions LLC
Oldsmar, FL 34677 | dermeleve.com +1 (877) 684-2299
U.S. Patents: 5,716,625; 5,804,203; 6,139,850; 7,404,967

NDC# XXXXX-XXX-XX



With SrX-38™
Feel the Difference

Dermeleve®

ADVANCED FORMULA

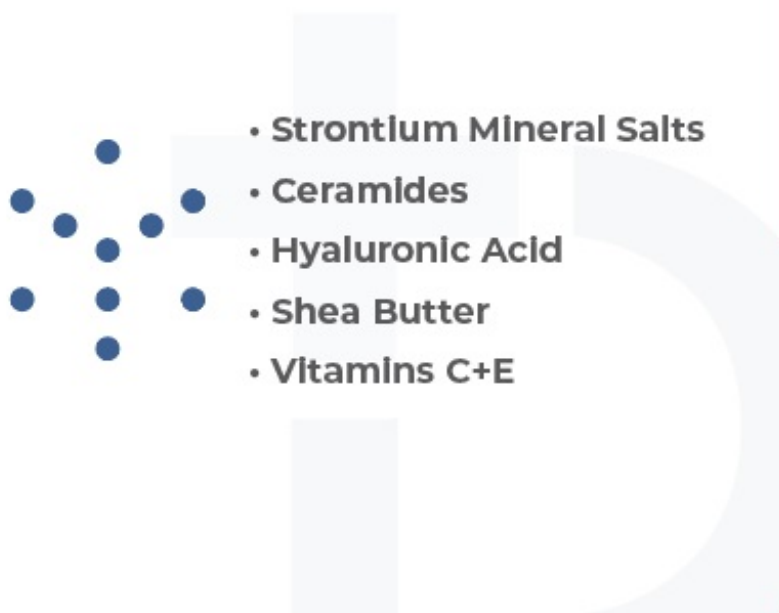
**Relieves dry, itchy
and irritated skin**

**Helps retain moisture in the skin
Aids skin barrier function**

STEROID FREE

With SrX-38™

Feel the Difference

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

Anti-Itch Cream

Made in USA

60g

Live Without Itch!

Dermeleve

ADVANCED FORMULA

**Steroid Free
Itch Relief Cream**

Dermeleve

Drug Facts	
Active Ingredient	Purpose
Pramoxine Hydrochloride (1%) External analgesic	
Uses	
■ For temporary relief of pain and itching associated with skin irritations, minor burns, sunburn, and rashes due to poison ivy, poison oak, or poison	
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	
Ascorbyl Tetraisopalmitate, Butyrospermum Parkii (shea) Butter, Caprylic/ Capric Triglyceride, Caprylyl Glycol, Ceraflame NG, Cetearyl Alcohol, Dimethicone, Disodium EDTA, Glycerin, Glyceryl Stearate, Isopropyl Myristate, Magnesium Aluminum Silicate, Phenoxethanol, Polyacrylate Crosspolymer-6, Polysorbate 60, Propylene Glycol, Sodium Hyaluronate, Strontium Nitrate, Tocopherol Acetate (Vitamin E), Water, Xanthan Gum	

NDC

Advanced Derm Solutions
Oldsmar, FL



With SrX-38[®]
Formulation

Made in USA Net Wt. 2g (0.07 oz)

TO ORDER, visit
www.dermeleve.com
or call: +1 (877) 684-2299

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



ADVANCED FORMULA

Relieves dry, itchy and irritated skin

Helps retain moisture in the skin
Aids skin barrier function

STEROID FREE

Contains

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



SrX-38™
Feel the Difference

Anti-Itch Cream

Made in USA

120g



Drug Facts	
Active Ingredient	Purpose
Pramoxine Hydrochloride (1%) External analgesic	
Uses	
■ For temporary relief of pain and itching associated with skin irritations, minor burns, sunburn, and rashes due to poison ivy.	
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	
Ascorbyl Tetraisopalmitate, Butyrospermum Parkii (shea) Butter, Caprylic/ Capric Triglyceride, Caprylyl Glycol, Ceramide NG, Cetearyl Alcohol, Dimethicone, Disodium EDTA, Glycerin, Glyceryl Stearate, Isopropyl Myristate, Magnesium Aluminum Silicate, Phenoxyethanol, Polyacrylate Crosspolymer-6, Polysorbate 60, Propylene Glycol, Sodium Hyaluronate, Strontium Nitrate, Tocopherol Acetate (Vitamin E), Water, Xanthan Gum	
Questions? Visit www.dermeleve.com or call +1 (877) 684-2299	

NDC# xxxxxxxx

Manufactured for Advanced Derm Solutions LLC
Oxnard, FL 34677 | dermeleve.com
U.S. Patents: 5,716,625; 5,804,203; 6,139,850; 7,404,967



3 81507 00009 1



With SrX-38™
Feel the Difference

Dermeleve®

Anti-Itch Cream

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 Anti-Itch 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 Anti-Itch 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

Dermeleve®

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



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

Anti-Itch Cream

Made in USA

120g

Dermeleve[®]

Drug Facts

Active Ingredient

Pramoxine Hydrochloride (1%)

Purpose

External analgesic

Uses

- For temporary relief of pain and itching associated with skin irritations, minor burns, sunburn, and rashes due to poison ivy, poison oak, or poison sumac

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

Ascorbyl Tetraispalmitate, Butyrospermum Parkii (shea) Butter, Caprylic/ Capric Triglyceride, Caprylyl Glycol, Ceramide NG, Cetearyl Alcohol, Dimethicone, Disodium EDTA, Glycerin, Glyceryl Stearate, Isopropyl Myristate, Magnesium Aluminum Silicate. Phenoxvethanol.

Magnesium Lactate Glycinate, Potassium Citrate,
Polyacrylate Crosspolymer-6, Polysorbate 60, Propylene
Glycol, Sodium Hyaluronate, Strontium Nitrate,
Tocopherol Acetate (Vitamin E), Water, Xanthan Gum

**Questions? Visit www.dermeleve.com
or call +1 (877) 684-2299**

Manufactured for Advanced Derm Solutions LLC
Oldsmar, FL 34677 | dermeleve.com +1 (877) 684-2299
U.S. Patents: 5,716,625; 5,804,203; 6,139,850; 7,404,967

NDC# 81507-003-01



With SrX-38™
Feel the Difference

Dermeleve®

ADVANCED FORMULA

Relieves dry, itchy

and irritated skin

Helps retain moisture in the skin
Aids skin barrier function

STEROID FREE

Contains

- **Strontium Mineral Salts**
- **Ceramides**
- **Hyaluronic Acid**
- **Shea Butter**
- **Vitamins C+E**



SrX-38™

Anti-Itch Cream

Made In USA

60g

Dermeleve®

Drug Facts

Active Ingredient

Pramoxine Hydrochloride (1%) External analgesic

Purpose

Uses

■ For temporary relief of pain and itching associated with skin irritations, minor burns, sunburn, and rashes due to poison ivy, poison oak, or poison sumac

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

Ascorbyl Tetraispalmitate, Butyrospermum Parkii (shea) Butter, Caprylic/ Capric Triglyceride, Caprylyl Glycol, Ceramide NG, Cetearyl Alcohol, Dimethicone, Disodium EDTA, Glycerin, Glyceryl Stearate, Isopropyl Myristate, Magnesium Aluminum Silicate, Phenoxyethanol, Polyacrylate Crosspolymer-6, Polysorbate 60, Propylene Glycol, Sodium Hyaluronate, Strontium Nitrate, Tocopherol Acetate (Vitamin E), Water, Xanthan Gum

Questions? Visit www.dermeleve.com
or call +1 (877) 684-2299

NDC# XXXXXXXXX

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



With CrY 30™

With SrX-38™
Feel the Difference

Dermeleve®

Anti-Itch Cream

For all skin types

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

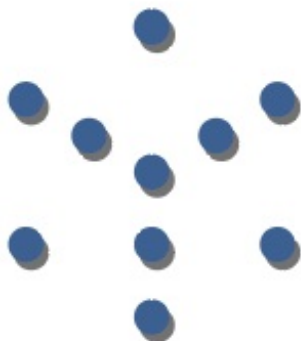
Dermeleve®

Dermeleve® is formulated for dry and itchy skin using the latest advancements in dermatological science. Dermeleve® ADVANCED FORMULA Anti-Itch 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
Anti-Itch Cream can help



Store below 75°F / 24°C

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

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.



3 81507 00012 1

Advanced Derm Solutions LLC

Made in USA 60g

DERMELEVE

pramoxine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81507-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CAPRYLIC/CAPRIC MONO/DI-GLYCERIDES (UNII: U72Q2I8C85)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE 100 (UNII: RO266O364U)	
POLYACRYLIC ACID (450000 MW) (UNII: KD3S7H73D3)	
HYALURONIC ACID (UNII: S270N0TRQY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

POLAWAX POLYSORBATE (UNII: Q504PL8E0V)
GLYCERIN (UNII: PDC6A3C0OX)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
XANTHAN GUM (UNII: TTV12P4NEE)
CERAMIDE NG (UNII: C04977SRJ5)
WATER O-18 (UNII: 7QV8F8BYNJ)
MAGNESIUM ALUMINUM SILICATE TYPE IA (UNII: SUS08ZOA9S)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
EDETATE DISODIUM (UNII: 7FLD91C86K)
TOCOPHEROL (UNII: R0ZB2556P8)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
STRONTIUM NITRATE (UNII: BDG873AQZL)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81507-005-01	1 in 1 BOX	11/01/2024	
1		60 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:81507-005-02	1 in 1 BOX	11/01/2024	
2		120 g 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 Drug	M016	11/01/2024	

Labeler - Advanced Derm Solutions LLC (117840544)

Revised: 8/2024

Advanced Derm Solutions LLC