

DERMASO PLUS CREAM- dressing, wound, drug
Aletris Pharmaceuticals, LLC

Dermaso Plus™ Cream

Indications for Use

Under the supervision of a healthcare professional, Dermaso Plus™ Cream is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. Dermaso Plus™ Cream also helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Device Description

Dermaso Plus™ Cream is a non-sterile, white to off-white, low odor, fragrance free, topical product. The Dermaso Plus™ Cream forms a physical barrier that helps to maintain a moist wound and skin environment. Dermaso Plus™ Cream is a prescription device.

Contraindications

Dermaso Plus™ Cream is contraindicated in persons with a known hypersensitivity to any of the components of the formulation.

Warnings

Use only as directed. Keep out of the reach of children. Avoid contact with eyes. For topical use only. Not for ophthalmic use. Do not apply within four hours prior to a radiation session.

Precautions and Observations

- Dermaso Plus™ Cream does not contain a sunscreen and should not be used prior to extended exposure to the sun.
- If clinical signs of infection are present, appropriate treatment should be initiated; use of Dermaso Plus™ Cream may be continued during the anti-infective therapy.
- If the condition does not improve within 10-14 days, consult a physician.
- Dermaso Plus™ Cream may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

Instructions for Use

Dispense Dermaso Plus™ Cream into palm of hand and apply to affected area 3 times per day, or as directed by a physician. Massage gently into the skin until completely absorbed. If the skin is broken, cover with appropriate dressing. Dermaso Plus™ Cream

is non-sterile.

Ingredients

Water, Glycerin, Ethylhexyl Palmitate, Cetearyl Alcohol, Propylene Glycol, Dicapryl Phosphate, Theobroma Grandiflorum Seed Butter, Petrolatum, Dimethicone, Steareth-10, Ceteareth-10 Phosphate, Hydroxypropyl Bispalmitamide MEA (Ceramide), Tocopheryl Acetate, Methylparaben, Disodium EDTA, Propylparaben, Sodium Hyaluronate and Sodium Hydroxide.


How Supplied

Dermaso Plus™ Cream is available in 450g commercial jars. 450g jar may be used for up to 60 days after opening.

CAUTION: Federal law restricts this device to sale by or on the order of a physician or other licensed health care practitioner.

Store between 59°F - 86°F (15°C - 30°C).

Dermaso Plus™ Cream Net Weight: 450g

Dermaso Plus™ Cream 

60010-89073
ALETRIS PHARMACEUTICALS
Dermaso Plus™ Cream

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Peel label to see package insert for full discussion of indications, directions, contraindications, and warnings.
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Symptom Relief for:

- Atopic Dermatitis
- Allergic Contact Dermatitis
- Radiation Dermatitis

MANUFACTURED FOR:
ALETRIS PHARMACEUTICALS
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Biloxi, MS 39532
(228) 207-8112
www.alettrispharma.com

Rx Only Net Wt. 450g

Place Sticker Here

DERMASO PLUS CREAM

dressing, wound, drug

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	GS1:86001089073
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	GS1:86001089073	1 in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K150914	11/07/2023	

Labeler - Aletris Pharmaceuticals, LLC (118956541)

Revised: 4/2020

Aletris Pharmaceuticals, LLC