

HYLAGUARD CREAM- dressing, wound, drug

Lacer Pharma LLC

Hylaguard Cream

Indications for Use

Under the supervision of a healthcare professional, Hylaguard 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. Hylaguard 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

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

Contraindications

Hylaguard 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

- Hylaguard 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 Hylaguard Cream may be continued during the anti-infective therapy.
- If the condition does not improve within 10-14 days, consult a physician.
- Hylaguard Cream may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

Instructions for Use

Dispense Hylaguard 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. Hylaguard Cream is non-sterile.

Ingredients

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

How Supplied

Hylaguard 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).

Hylaguard Cream Net Weight: 450g

Hylaguard Cream

LACER PHARMA™

INDICATIONS FOR USE: Under the supervision of a healthcare professional, Hylaguard 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. Hylaguard Cream helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

INSTRUCTIONS FOR USE: Dispense Hylaguard Cream into the palm of hand and apply to the 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. Hylaguard 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 Bispharmalimide MEA (Ceramides), Tocopheryl Acetate, Methylparaben, Disodium EDTA, Propylparaben, Sodium Hyaluronate and Sodium Hydroxide.

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.

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

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

Symptom Relief for:

- Atopic Dermatitis
- Allergic Contact Dermatitis
- Radiation Dermatitis

Hylaguard Cream

Rx Only

Net Wt. 450g

60003-56490

Symptom Relief for:

- Atopic Dermatitis
- Allergic Contact Dermatitis
- Radiation Dermatitis

MANUFACTURED FOR:

LACER PHARMA™

Lacer Pharma, LLC
996 N. Halstead Road, Suite D
Ocean Springs, MS 39564
(951) 323-6919
www.lacerpharma.com

HYLAGUARD CREAM

dressing, wound, drug

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	GS1:860003564905
---------------------	-----------------------------	---------------------------	------------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	GS1:860003564905	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	05/15/2020	

Labeler - Lacer Pharma LLC (117072266)

Revised: 4/2020

Lacer Pharma LLC