

**HPRPLUS CREAM- dressing, wound, drug
PruGen, Inc.**

HPRplus cream

INDICATIONS FOR USE

HPRplus 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. HPRplus also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

CONTRAINDICATIONS

HPRplus 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.

HPRplus Emollient Foam:

Contents under pressure.

Do not puncture or incinerate container.

Do not expose to temperatures above 120°F (49°C).

PRECAUTIONS AND OBSERVATIONS

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

DIRECTIONS-CREAM:

Dispense HPRplus 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.

DIRECTIONS-EMOLLIENT FOAM:

Important: Prime Can Before Initial Use.

To Prime Can: Shake can vigorously (until product moves inside can). Firmly strike bottom of can onto palm of other hand or a hard surface at least 3 times. Hold the can upright and direct initial spray to a non-skin surface. Until foam dispenses, DO NOT spray directly on the skin as the initial spray may expel cold liquid propellant. Press down on actuator for 1-3 seconds until foam begins to dispense. If foam does not dispense within 3 seconds, prime can again.

Before Each Use: Shake can vigorously. Firmly strike bottom of can onto palm of other hand or a hard surface at least 3 times.

During Use: Holding can upright, dispense HPRplus Emollient Foam 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. Wipe off any excess foam from actuator after use.

INGREDIENTS

Water, Glycerin, Ethylhexyl Palmitate, Cetearyl Alcohol, Propylene Glycol, Dicapryl 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. *HPRplus Emollient Foam also contains Hydrofluorocarbon 134a (propellant).*

HOW SUPPLIED

HPRplus Cream is available in 100 g tubes (NDC 42546-030-10) and 450 g jars (NDC 42546-030-45).

HPRplus Emollient Foam is available in 100 g (NDC 42546-025-10) and 150 g (NDC 42546-025-15) canisters.

HPRplus Emollient Foam will not dispense entire contents. Container is overfilled to guarantee dispensing at least the listed amount.

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° and 86°F (15° and 30°C). Protect from freezing.

HPRplus Emollient Foam: Store upright.

Manufactured for:

PruGen, Inc. Pharmaceuticals

Scottsdale, AZ 85255

www.prugen.com

PRINCIPAL DISPLAY PANEL - 100 g Tube Box

42546-030-10

Rx Only

HPR
PLUS™
CREAM

Net Weight 100 g

HPR
PLUS
CREAM

42546-030-10

Rx Only

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Manufactured for:
PruGen, Inc. Pharmaceuticals
Scottsdale, AZ 85255
www.pru-gen.com

PRUGEN
PHARMACEUTICALS

Rev 3.0

Net Weight 100 g

42546-030-10

Rx Only

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See package insert for full discussion of indications, directions, contraindications, and warnings.

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PRUGEN
PHARMACEUTICALS

Net Weight 100 g





HPRPLUS CREAM

dressing, wound, drug

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:42546-030
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42546-030-10	1 in 1 BOX		
1		100 g in 1 TUBE; Type 0: Not a Combination Product		
2	NHRIC:42546-030-45	1 in 1 BOX		
2		450 g 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	K113774	03/01/2012	

Labeler - PruGen, Inc. (929922750)

Revised: 7/2018

PruGen, Inc.