

**HPR EMOLLIENT FOAM- dressing, wound, drug  
PruGen, Inc.**

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**HPR Emollient Foam**

**INDICATIONS FOR USE**

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

**CONTRAINDICATIONS**

HPR Emollient Foam 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.

Contents under pressure.

Do not puncture or incinerate container.

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

**PRECAUTIONS AND OBSERVATIONS**

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

**DIRECTIONS**

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 HPRTM 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, Hydrofluorocarbon 134a (propellant), Glycerin, Ethylhexyl Palmitate, Cetearyl Alcohol, Propylene Glycol, Dicapryl Phosphate, Theobroma Grandiflorum Seed Butter, Petrolatum, Dimethicone, Steareth-10, Cetareth-10 Phosphate, Tocopheryl Acetate, Methylparaben, Disodium EDTA, Propylparaben, Sodium Hyaluronate and Sodium Hydroxide.

## **HOW SUPPLIED**

HPR Emollient Foam is available in a 100 g canister (NDC 42546-020-10).

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. Store upright.

Manufactured for:

PruGen, Inc. Pharmaceuticals

8714 E Vista Bonita Dr

Scottsdale, AZ 85255

[www.pru-gen.com](http://www.pru-gen.com)

## **PR Cream Box Label**

NDC 42546-135-04

PR cream Nonsteroidal Cream

For Topical Dermatological Use Only

Dispense as a complete kit

Kit includes:

-2 tubes PR cream - 2oz. (56.7g)

-2 tubes PruDrate moisturizing cream - 2oz. (56.7g)

- Patient Instructions

Rx Only

PruGen, Inc. Pharmaceuticals



EMOLLIENT FOAM

**HPR**<sup>TM</sup>

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Rev 1.1

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

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42546-020-10

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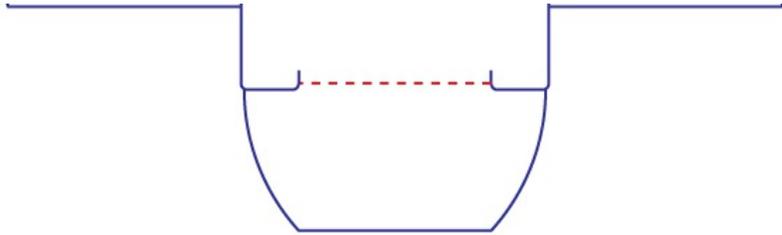
Rx Only

Rx Only

Net Weight 100 g

Net Weight 100 g





## HPR EMOLLIENT FOAM

dressing, wound, drug

### Product Information

<b>Product Type</b>	PRESCRIPTION MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:42546-020
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42546-020-10	1 in 1 BOX		
1		100 g in 1 CANISTER		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K113772	02/01/2012	

**Labeler** - PruGen, Inc. (929922750)

Revised: 9/2012

PruGen, Inc.