

**HPRPLUS - MB HYDROGEL KIT- dressing, wound, drug
PruGen, Inc.**

HPRplus - MB HydroGel Kit

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-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 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

8714 E Vista Bonita Dr

Scottsdale, AZ 85255

www.prugen.com

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - HPRplus - MB HydroGel Kit Carton Label

NDC 42546-026-10

HPRplus - MB HydroGel Kit

CONVENIENCE KIT INCLUDES:

1 Canister (100g) of HPRplus Emollient Foam

1 Bottle (225g) of MB HydroGel

Dispense as a complete kit - Do not break up

Rx Only



PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - MB HydroGel Label

MB HydroGel

Intended for use to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.

225g

Step 1

APPLY FIRST

MBTM HydroGel

Intended for use to relieve itch and pain
from minor skin irritations, lacerations,
abrasions, and minor burns.

PRUGENTM
PHARMACEUTICALS

225 g

Rev 1.2

DIRECTIONS: Cleanse the area and blot dry. Apply a thin layer of MBTM HydroGel to the affected and immediately surrounding area. Use once or twice daily or as directed by physician. Cover with a bandage if necessary.

INTENDED USE: MBTM HydroGel is intended for use to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.

WARNING: For external use only. Not for injection. Do not use in the eyes. In case of deep or puncture wounds, animal bites or serious burns, consult a health care professional. Treatment of skin ulcers should be under the supervision of a healthcare professional. Stop use and consult a healthcare professional (1) if the condition persists, (2) signs of infection occur (e.g., increased pain, bleeding, wound drainage), (3) there is a change in wound color and/or odor, (4) the wound continues to get larger after the few first signs of healing, and (5) the wound does not begin to show signs of healing. If condition persists for longer than 7 days, consult a healthcare professional.
Keep out of the reach of children.

HANDLING: No special handling precautions required.

STORAGE: Store with cap closed tightly after each use in its original container at room temperature away from direct sunlight and heat. Do not freeze.

DISPOSAL: No special disposal considerations required.

INGREDIENTS: Electrolyzed Water (96.524%), Sodium Magnesium Fluorosilicate (3.000%), Sodium Phosphate (0.400%), Sodium Chloride (0.066%), Hypochlorous Acid (0.008%), and Sodium Hypochlorite (0.002%). The gel contains hypochlorous acid and sodium hypochlorite as preservatives to reduce/prevent growth of microorganisms within the gel. The effect of this product in the wound bed has not been clinically tested.

Manufactured for
PruGen, Inc. Pharmaceuticals
8714 E Vista Bonita Dr
Scottsdale, AZ 85255
www.pru-gen.com

Rev 1.0

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - HPRplus Emollient Foam 100 Gram Canister

NDC 42546-025-10

Rx Only

Net Wt 100g

42546-025-10

INGREDIENTS:

Water, Hydrofluorocarbon 134a (propellant), 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.

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).

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

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

Store between 59° and 86°F (15° and 30°C).
 Protect from freezing. Store upright.

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 Scottsdale, AZ 85255
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Rev 1.1



INDICATIONS FOR USE:

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

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 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.

Will not dispense entire contents. Container is overfilled to guarantee dispensing at least the listed amount.

Rx Only

Net Weight 100 g

HPRPLUS - MB HYDROGEL KIT

dressing, wound, drug kit

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:42546-026
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42546-026-10	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
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Part 1	1 CANISTER	100 g
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Part 1 of 1

HPRPLUS

dressing, wound, drug aerosol, foam

Product Information

Item Code (Source)	NHRIC:42546-025
Route of Administration	TOPICAL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42546-025-10	100 g in 1 CANISTER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Premarket Notification	K113774	03/01/2012	

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Premarket Notification	K113774	03/01/2012	

Labeler - PruGen, Inc. (929922750)