

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

**HPRplus - HydroGel Kit
PruGen PruGen, Inc. Pharmaceuticals**

FOR TOPICAL DERMATOLOGICAL AND EXTERNAL USE ONLY.

Rx Only

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™ HydroGel is available in 225mL bottles (NDC 42546-033-99)

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 59⁰ and 86⁰ F (15⁰ and 30⁰ C). Protect from freezing.

HPRplus™ Emollient Foam: Store upright.

Manufactured for:

PruGen, Inc. Pharmaceuticals

Scottsdale, AZ 85255

www.pru-gen.com

Rev 2.0

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC 42546-033-10

HPR

PLUS™

HydroGel KIT

CONVENIENCE KIT INCLUDES:

1 Bottle (225 ml) of HPRplus™ HydroGel

1 Tube (100 g) of HPRplus™ Cream

Dispense as a complete kit - Do not break up

Rx Only

PRuGEN®

PHARMACEUTICALS

NDC 42546-033-10

HPR PLUSTM HydroGel KIT

CONVENIENCE KIT INCLUDES:

- 1 Bottle (225 ml) of HPRplusTM HydroGel
- 1 Tube (100 g) of HPRplusTM Cream

Dispense as a complete kit - Do not break up

Rx Only



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

DIRECTIONS: Dispense HPRplusTM 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.

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.

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.

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.

The logo for PRUGEN PHARMACEUTICALS features a circular icon containing a stylized 'P' and 'G' symbol. To the right of the icon is the word 'PRUGEN' in a bold, sans-serif font, with 'PHARMACEUTICALS' in a smaller font below it.
PRUGEN[®]
PHARMACEUTICALS



CONVENIENCE KIT INCLUDES:
1 Bottle (225 ml) of HPRplus™ HydroGel
1 Tube (100 g) of HPRplus™ Cream



NDC 42546-033-10



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

INGREDIENTS: Sodium Magnesium Fluorosilicate, Cyclomethicone, Phosphoric Acid, Sodium Chloride, Sodium Bicarbonate, Hypochlorous Acid, Water.

The effect of this product in the wound bed has not been clinically tested.

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

CONVENIENCE KIT INCLUDES:

- 1 Bottle (225 ml) of HPRplus™ HydroGel
- 1 Tube (100 g) of HPRplus™ Cream

Dispense as a complete kit - Do not break up

Rx Only

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 treatments, 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 sun- light and heat. Do not freeze.

DISPOSAL: No special disposal considerations required.

Kit manufactured for: PruGen, Inc. Pharmaceuticals
Scottsdale, AZ 85255
www.pruGen.com
Rev 5.0



HPRPLUS - MB HYDROGEL

dressing, wound, drug kit

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:42546-033
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42546-033-10	1 in 1 CARTON; Type 0: Not a Combination Product		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	100 g
Part 2	1 BOTTLE	225 mL

Part 1 of 2

HPRPLUS

dressing, wound, drug aerosol, foam

Product Information

Item Code (Source)	NHRIC:42546-030
Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0K00R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	ETHYLHEXYL PALMITATE (UNII: 2865993309)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
INGR	THEOBROMA GRANDIFLORUM SEED BUTTER (UNII: I711F13FXM)	
INGR	PETROLATUM (UNII: 4T6H12BN9U)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	STEARETH-10 (UNII: FD0913P475)	
INGR	CETEARETH-10 PHOSPHATE (UNII: 099WOY1SA3)	
INGR	HYDROXYPROPYL BISPALMITAMIDE MONOETHANOLAMIDE (UNII: EVX7NC9YVE)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	NORFLURANE (UNII: DH9E53K1Y8)	

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 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
PREMARKET NOTIFICATION	K113774	04/15/2015	

Part 2 of 2

MB HYDROGEL

dressing, wound, drug gel

Product Information

Item Code (Source)	NHRIC:42546-033
Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0K00R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	ETHYLHEXYL PALMITATE (UNII: 2865993309)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
INGR	THEOBROMA GRANDIFLORUM SEED BUTTER (UNII: I711F13FXM)	
INGR	PETROLATUM (UNII: 4T6H12BN9U)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	STEARETH-10 (UNII: FD0913P475)	
INGR	CETEARETH-10 PHOSPHATE (UNII: 099WOY1SA3)	
INGR	HYDROXYPROPYL BISPALMITAMIDE MONOETHANOLAMIDE (UNII: EVX7NC9YVE)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42546-033-99	225 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
PREMARKET NOTIFICATION	K113774	04/15/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
PREMARKET NOTIFICATION	K113774	04/15/2015	

Labeler - PruGen, Inc. (929922750)

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PruGen, Inc.