

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

PR Cream Nonsteroidal Cream

PRODUCT DESCRIPTION

PR cream is a non-sterile cream formulation intended for prescription use only.

INDICATIONS & USAGE

PR cream is indicated to manage various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and irritant contact dermatitis. PR cream helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

DIRECTIONS FOR USE:

Apply a thin layer to affected areas 2-3 times per day or as directed by a physician.

INGREDIENTS

PR cream is a nonsteroidal cream comprised of aluminum magnesium hydroxide stearate, cetyl dimethicone copolyol, cyclomethicone, dimethicone, hexyl laurate, polyglyceryl-4-isostearate, purified water, and sodium chloride. Contains phenoxyethanol and propylparaben as preservatives.

CONTRAINDICATIONS

PR cream is contraindicated in persons with a known hypersensitivity to any of the components of the formulation.

PRECAUTIONS

For external use only. Avoid contact with eyes and other mucous membranes. Do not use the product if the packaging is damaged or after the expiration date. If your condition does not improve within 10-14 days, consult a physician. The safety and efficacy of PR cream has not been determined in pediatric patients.

Keep out of the reach of children.

PR cream contains no dyes or fragrances and is well tolerated and safe.

HOW SUPPLIED

PR cream is available in a kit (NDC 42546-135-04) including two net wt. 2oz. (56.7g) tubes (NDC 42546-135-02) with two complimentary net wt. 2 oz. (56.7g) tubes of PruDrate® moisturizing cream.

Store at temperatures between 68° - 77°F (20° - 25°C). Do not freeze.

Manufactured for:

PruGen, Inc. Pharmaceuticals

8711 East Pinnacle Peak Road Suite C-201 P.M.B 225

Scottsdale, AZ 85255

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



PR CREAM				
dressing, wound, drug				
Product Information				
Product Type	PRESCRIPTION MEDICAL DEVICE		Item Code (Source)	NHRIC:42546-135
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42546-135-04	2 in 1 BOX		
1		56.7 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K093159	07/01/2010	

Labeler - PruGen, Inc. (929922750)

Revised: 9/2012

PruGen, Inc.