

**PRUCLAIR- dressing, wound, drug
PruGen, Inc.**

PruClair Nonsteroidal Cream

INDICATIONS & USAGE

Under the supervision of a healthcare professional, PruClair nonsteroidal cream is indicated to manage various types of dermatoses.

DIRECTIONS FOR USE:

Apply PruClair nonsteroidal cream to the affected skin areas 2 to 3 times a day (or as needed), and massage gently into the skin. If the skin is broken, cover PruClair nonsteroidal cream with a dressing of choice.

INGREDIENTS

PruClair is an off-white, nonsteroidal cream comprised of Purified water, Ethylhexyl palmitate, Pentylene glycol, Butyrospermum parkii, Glyceryl stearate, PEG-100 stearate, Arachidyl glucoside, Behenyl alcohol, Arachidyl alcohol, Bisabolol, Glycyrrhetic acid, Carbomer, Allantoin, DMDM hydantoin, Sodium hydroxide, Disodium EDTA, Capryloyl Glycine, Vitis vinifera, Ascorbyl tetraisopalmitate, Piroctone olamine, Propyl Gallate, Ethylhexylglycerin, Sodium hyaluronate, Telmestaine, Tocopheryl Acetate, Butylene glycol.

CAUTIONS

PruClair nonsteroidal cream does not contain milk, wheat, peanut, or animal derivatives. PruClair nonsteroidal cream does contain shea butter (*Butyrospermum parkii*), a derivative of shea nut oil (not peanut oil). Patients with a known allergy to nuts or nut oils should consult their doctor before using this topical preparation.

Do not use the product if the packaging is damaged or after expiration date. Store at room temperature up to 25°C (77°F). Do not freeze.

OTHER PATIENT INFORMATION

The formulation contains no dyes or fragrances and is well tolerated and safe for patients of all ages. PruClair nonsteroidal cream does not contain milk, wheat or animal derivatives.

HOW SUPPLIED

100g tube (NDC 42546-412-11)

Manufactured for:
PruGen, Inc. Pharmaceuticals
8714 E Vista Bonita Dr
Scottsdale, AZ 85255

PruClair Carton Label

NDC 42546-412-11

PruClair Nonsteroidal Cream

For Topical Dermatological and External Use Only

Rx Only

100g

PruGen, Inc. Pharmaceuticals

PruClair™
NONSTEROIDAL CREAM

PRUGEN™
PHARMACEUTICALS

NDC 42546-412-11

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PruClair™
NONSTEROIDAL CREAM

AVOID CONTACT WITH EYES.

Indications for Use:

Under the supervision of a healthcare professional, PruClair™ nonsteroidal cream is indicated to manage various types of dermatoses.

Directions for Use: Apply PruClair™ nonsteroidal cream to the affected skin areas 2 to 3 times a day (or as needed), and massage gently into the skin. If the skin is broken, cover PruClair™ nonsteroidal cream with a dressing of choice.

Precautions: Do not use the product if the packaging is damaged or after expiration date. Store at room temperature up to 25°C (77°F). Do not freeze.

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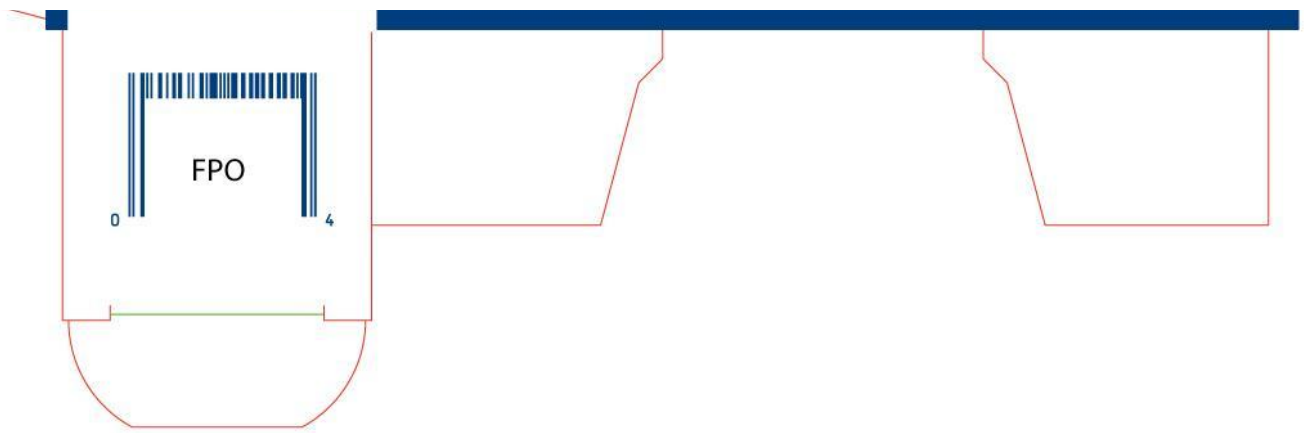
Cautions: The use of PruClair™ nonsteroidal cream is contraindicated in any patient with a known history of hypersensitivity to any of the ingredients. PruClair™ nonsteroidal cream does not contain milk, wheat, peanut, or animal derivatives. PruClair™ nonsteroidal cream does contain shea butter (Butyrospermum parkii), a derivative of shea nut oil (not peanut oil). Patients with a known allergy to nuts or nut oils should consult their physician before using this topical preparation.

Federal law restricts PruClair™ to sale by or on the order of a physician or properly licensed practitioner.

Rev 5.8

PRUGEN™
PHARMACEUTICALS

PRUGEN™
PHARMACEUTICALS



PRUCLAIR

dressing, wound, drug

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:42546-412
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42546-412-11	1 in 1 BOX		
1		100 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K093156	06/01/2010	

Labeler - PruGen, Inc. (929922750)

Revised: 9/2012

PruGen, Inc.