

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

PruMyx External Cream

DESCRIPTION

PruMyx Cream is a fragrance free, preservative free, water-based emulsion formulated for the management and relief of the burning and itching experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. PruMyx Cream helps to relieve the dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

INDICATIONS & USAGE

PruMyx Cream is indicated to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. PruMyx Cream helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

CONTRAINDICATIONS

PruMyx Cream is contraindicated in persons with a known hypersensitivity to any of the components of the formulation.

WARNINGS

In radiation therapy, PruMyx Cream may be applied as indicated by the treating Radiation Oncologist. Do not apply 4 hours prior to a radiation session.

PRECAUTIONS AND OBSERVATIONS

- PruMyx Cream is for external use only.
- PruMyx Cream 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 PruMyx Cream may be continued during the anti-infective therapy.
- If the condition does not improve within 10 – 14 days, consult a physician.
- Keep this and other similar products out of the reach of children.
- PruMyx Cream may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

INSTRUCTIONS FOR USE

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

INGREDIENTS

PruMyx Cream contains purified water, olive oil, glycerin, pentylene glycol, palm glycerides, vegetable oil, hydrogenated lecithin, squalane, betaine, palmitamide MEA, sarcosine, acetamide MEA, hydroxyethyl cellulose, sodium carbomer, carbomer, xanthan gum.

HOW SUPPLIED

PruMyx Cream is available in a 140 gram tube, NDC 42546-710-05.

Store at 15°C to 30°C (59°F to 86°F). Do not freeze.

PruGen, Inc. Pharmaceuticals
8711 East Pinnacle Peak Road
Suite C-201 P.M.B.225
Scottsdale, AZ 85255

PruMyx Carton Label

NDC 42546-710-05

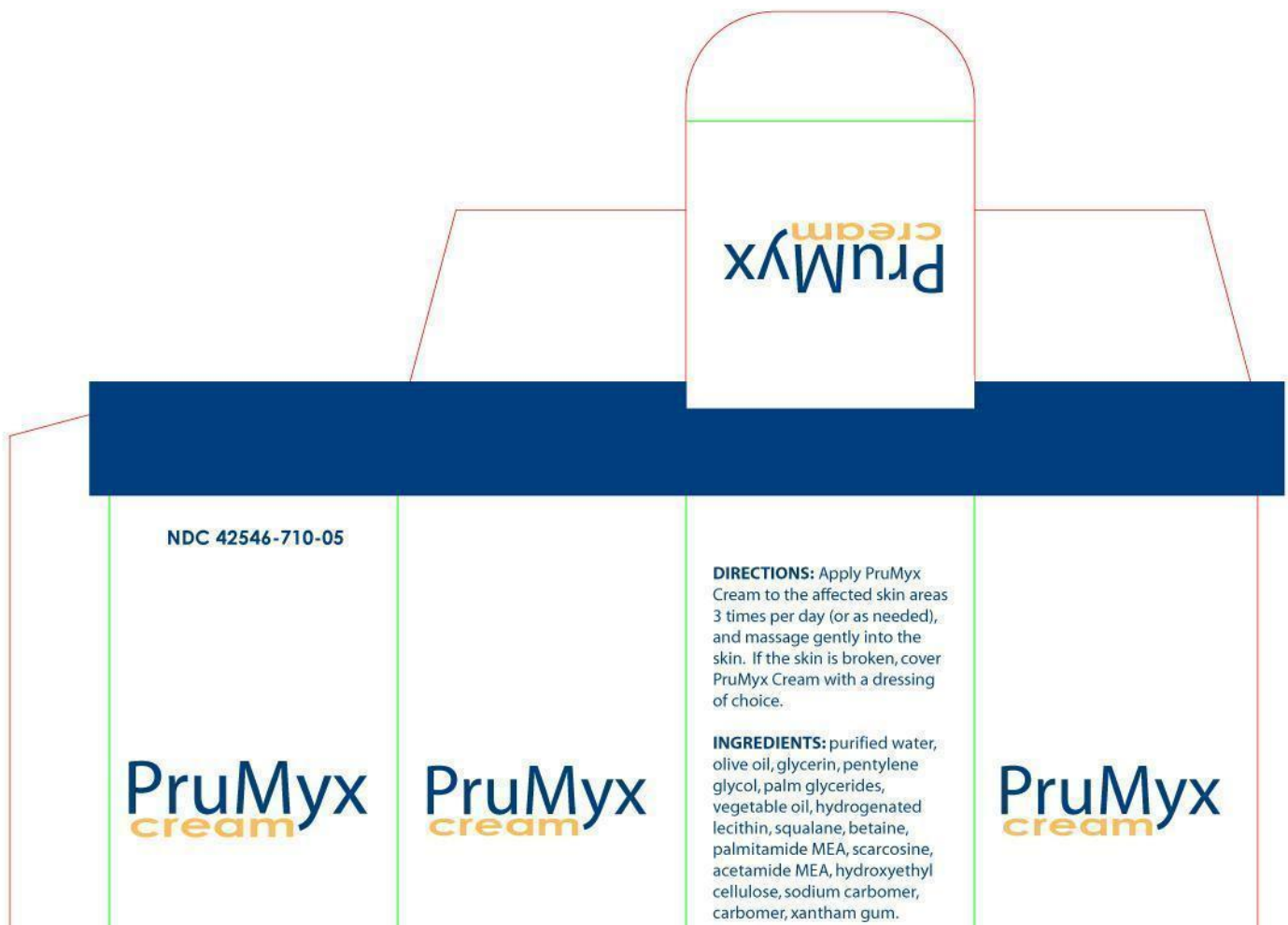
PruMyx Cream

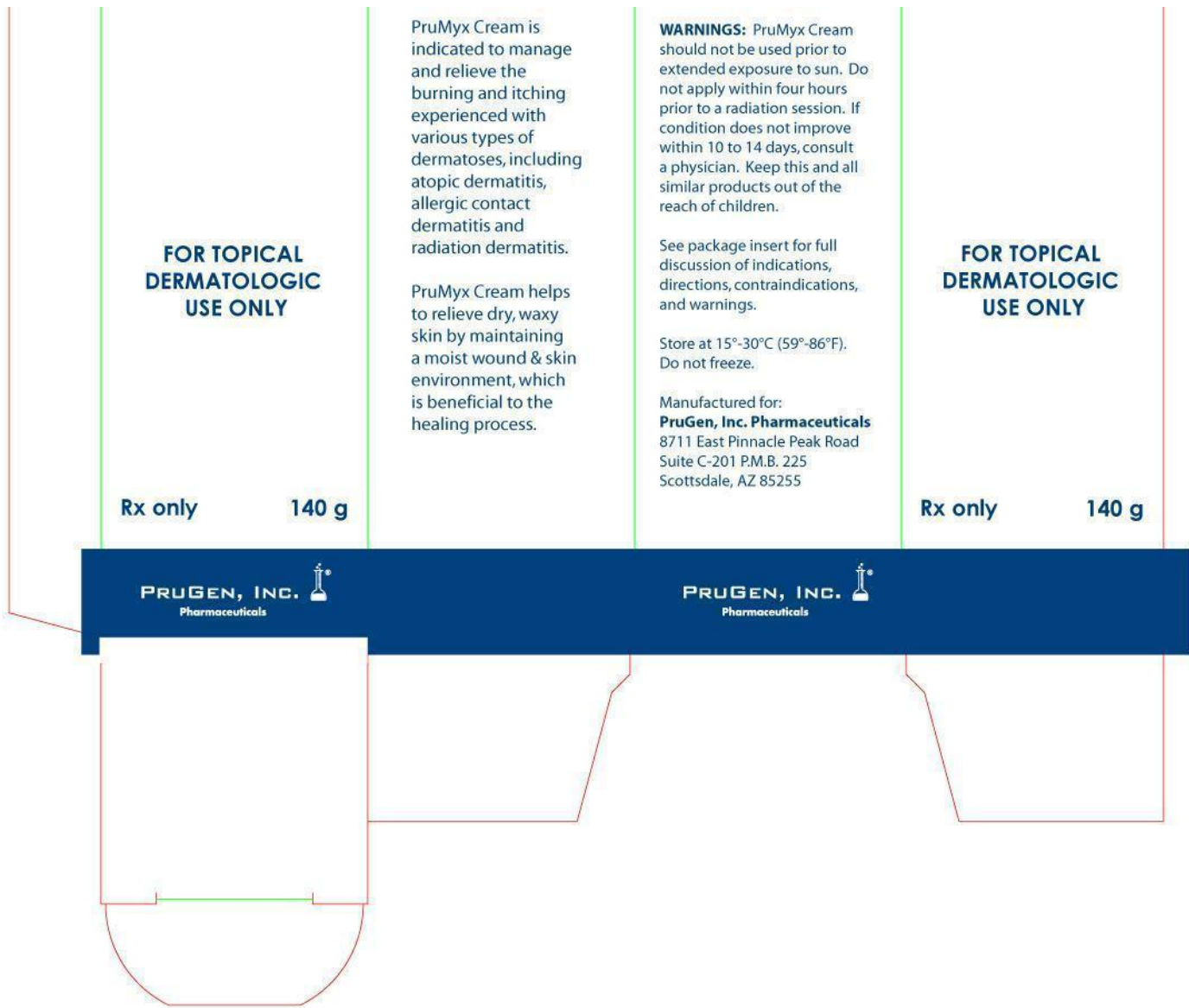
For Topical Dermatologic Use Only

Rx Only

140g

PruGen, Inc. Pharmaceuticals





PRUMYX

dressing, wound, drug

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:42546-710
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42546-710-05	1 in 1 BOX		
1		140 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K082089	02/01/2009	

Labeler - PruGen, Inc. (929922750)

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PruGen, Inc.