

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

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**PruTect Topical Emulsion**

**DESCRIPTION**

PruTect™ is a water-based, non-sterile emulsion formulated for the dressing and management of superficial wounds, minor abrasions,

dermal ulcers, donor sites, 1st and 2nd degree burns, including sunburns, and radiation dermatitis. When applied properly to a wound,

PruTect™ provides an optimum moist environment for the healing process and isolates the wound from harmful germs and other external

contamination.

**INDICATIONS & USAGE**

PruTect™ is indicated for use in:

- Full Thickness Wounds, Pressure Sores, Dermal Ulcers including Lower Leg Ulcers
- Superficial Wounds
- 1st and 2nd Degree Burns, including Sunburns
- Dermal Donor and Graft Site Management
- Radiation Dermatitis
- Minor Abrasions

**CONTRAINDICATIONS**

PruTect™ is contraindicated for use on bleeding wounds, skin rashes related to food or medicine allergies, and when an allergy to one of the ingredients is known.

**WARNINGS**

- In radiation therapy, PruTect™ may be applied as directed by the treating physician. Do not apply 4 hours prior to a radiation session.
- Do not apply PruTect™ to dermal grafts until after the graft has successfully taken.
- Do not apply to the eyes or to mucous membranes.
- Not for internal use.
- Keep out of reach of children.

**PRECAUTIONS AND OBSERVATIONS**

- For the treatment of any dermal wound, consult a physician. Use PruTect™ only as directed.
- PruTect™ is non-toxic, it is for topical use only and should not be ingested or taken internally.

- PruTect™ does not contain a sunscreen and should not be used prior to extended exposure to the sun.
- The use of PruTect™ on skin rashes due to allergies has not been studied sufficiently and therefore is not recommended.
- Following the application of PruTect™ a temporary tingling sensation may occur (10 to 15 minutes).
- If clinical signs of infection are present, appropriate treatment should be initiated. If clinically indicated, use of PruTect™ may be continued during the anti-infective therapy.
- If condition does not improve within 10-14 days, consult a physician.
- PruTect™ may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

## **INSTRUCTIONS FOR USE**

PruTect™ is for topical use only as directed by a healthcare professional.

### **Wounds, Abrasions, Full Thickness Wounds, Dermal Graft Site Management and Donor Site Management**

- Wash the affected area(s) with saline, clean water, or a suitable wound cleanser.
- Apply PruTect™ on and around the affected area(s) in thick layers 1/4 to 1/2 inch thick.
- If applying gauze dressing, moisten the dressing lightly before application.
- Reapply PruTect™ as described above every 24 to 48 hours or as directed until the wound or lesion has healed fully.
- For donor site management, apply PruTect™ after skin removal and cover with a moist dressing. Reapply as directed.
- For dermal graft site management, apply PruTect™ to the graft site only after the graft has taken successfully. PruTect™ can be washed away with a saline solution or clean water without causing damage to the newly formed tissues.

### **1st and 2nd Degree Burns, Including Sunburns**

- Before application of PruTect™ to burns, take precaution in removing any clothing in the affected area(s).
- Apply PruTect™ as soon as possible on and around the affected area(s), in a thick 1/4 to 1/2 inch layer until the skin no longer absorbs the product. A white waxy residue may remain. If pain from the burn persists, apply thinner layers of PruTect™ until the pain has ceased.
- Continue to apply PruTect™ until the affected area(s) has healed completely.
- Application of PruTect™ to the affected area(s) should continue during any subsequent physical therapy treatments.

### **Radiation Dermatitis**

- Apply a generous amount of PruTect™ three times per day, seven days a week to the treated area(s), gently massaging the area(s) until PruTect™ is completely absorbed.
- PruTect™ may be applied as indicated by the treating physician (see **WARNINGS**).

- Continue to apply PruTect™ as described above until the skin has fully recovered.
- Do not interrupt applications during the course of radiation therapy, even for one day.
- Do not apply PruTect™ 4 hours prior to a radiation session.

## **INGREDIENTS**

PruTect™ contains purified water, liquid paraffin, ethylene glycol monostearate, stearic acid, propylene glycol, paraffin wax, squalane, avocado oil, trolamine/sodium alginate, triethanolamine, cetyl palmitate, methylparaben (sodium salt), sorbic acid (potassium salt), propylparaben (sodium salt), and fragrance.

## **HOW SUPPLIED**

PruTect™ is supplied in a 45-gram tube (NDC 42546-130-45) and a 90-gram tube (NDC 42546-130-90).

Store at room temperature, do not freeze.

Rx ONLY - Prescription Medical Device: Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Manufactured for:

PruGen, Inc. Pharmaceuticals  
8711 East Pinnacle Peak Road  
Suite C-201 P.M.B 225  
Scottsdale, AZ 85255  
Rev. 1.4

## **PruTect Carton Label**

NDC 42546-130-45

PruTect™

Topical Emulsion

Rx Only

45g

PruGen, Inc. Pharmaceuticals

# PruTect™

TOPICAL EMULSION

PRUGEN, INC.   
Pharmaceuticals

NDC 42546-130-45

PruTect™ is a prescription topical, non-sterile emulsion indicated for use in full thickness wounds, pressure sores, dermal ulcers including lower leg ulcers, superficial wounds, 1st and 2nd degree burns including sunburns, dermal donor site management, graft site management, radiation dermatitis, and minor abrasions.

**Warning: Keep out of reach of children.**  
Store at room temperature, do not freeze.

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

**INGREDIENTS:** PruTect™ contains purified water, liquid paraffin, ethylene glycol monostearate, stearic acid, propylene glycol, paraffin wax, squalane, avocado oil, tromamine/sodium alginate, triethanolamine, cetyl palmitate, methylparaben (sodium salt), sorbic acid (potassium salt), propylparaben (sodium salt), and fragrance.

Manufactured for:  
**Prugen, Inc. Pharmaceuticals**  
8711 East Pinnacle Peak Road  
Suite C-201 PM.B. 225  
Scottsdale, AZ 85255

Rev.1.2

**Directions:** For topical use only as directed by a health care professional.  
**For Use on Superficial Wounds and Full Thickness Wounds:** Wash affected area(s) with saline or suitable wound cleanser. Apply PruTect™ in thick layers (1/4 to 1/2 inch) on and around affected area(s). If applying gauze dressing, moisten the dressing lightly before application. Reapply every 24-48 hours, or as directed.  
**For Use on 1st and 2nd Degree Burns Including Sunburns:** Apply PruTect™ in thick layers (1/4 to 1/2 inch) on and around affected area(s) until it is absorbed into the skin. If pain is present, apply a thinner layer of PruTect™ to the affected area(s). Continue application until affected area(s) has healed completely.  
**For Use on Dermal Donor and Graft Sites:** For Dermal Donor sites, apply after skin removal and for graft sites, only apply after graft has taken successfully. Apply PruTect™ in thick layers (1/4 to 1/2 inch) on and around affected area(s). If applying gauze dressing, moisten the dressing lightly before application. Reapply as directed.  
**For Use on Radiation Dermatitis:** Apply PruTect™ generously three times daily to the radiation treated area(s) gently massaging the area(s) until it is absorbed. Continue application until the skin has fully recovered. Do not apply PruTect™ 4 hours prior to radiation session.

PruTect™  
TOPICAL EMULSION

Rx only

45g

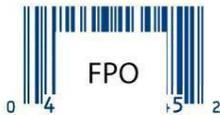
PruTect™  
TOPICAL EMULSION

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## PRUTECT

dressing, wound, drug

### Product Information

**Product Type**

PRESCRIPTION MEDICAL DEVICE

**Item Code (Source)**

NHRC:42546-130

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42546-130-45	1 in 1 BOX		
1		45 g in 1 TUBE		
2	NHRIC:42546-130-90	1 in 1 BOX		
2		90 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K092878	02/01/2010	

**Labeler** - PruGen, Inc. (929922750)

Revised: 8/2012

PruGen, Inc.