

**EMULSION SB- dressing, wound, drug  
PruGen, Inc.**

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**Emulsion SB External Emulsion**

**DESCRIPTION**

Emulsion SB is a steroid-free, fragrance-free, ceramide formulation.

**INDICATIONS & USAGE**

Emulsion SB is to be used to treat dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, and radiation dermatitis. Emulsion SB helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

**CONTRAINDICATIONS**

Emulsion SB is contraindicated in persons with known hypersensitivity to any of the components of the formulation.

**WARNINGS**

- Emulsion SB does not contain a sunscreen and should always be used in conjunction with a sunscreen in sun exposed areas
- Do not apply within 4 hours prior to radiation therapy
- Keep this and similar products out of the reach of children
- Follow directions for use
- If condition does not improve within 10 to 14 days, consult physician

**PRECAUTIONS AND OBSERVATIONS**

For the treatment of any dermal wound, consult a physician.

- Use Emulsion SB only as directed
- Emulsion SB is for external use only and should not be ingested or taken internally
- If clinical signs of infection are present, appropriate treatment should be initiated. If clinically indicated, use of Emulsion SB may be continued during the anti-infective therapy
- In radiation dermatitis and/or in conjunction with ongoing radiation therapy, apply following radiation therapy or as indicated by the radiation therapist

**INSTRUCTIONS FOR USE**

Apply a thin layer to the affected skin areas 2 times per day (or as needed or directed by your physician) and massage gently into the skin. If the skin is broken, cover Emulsion SB with a dressing of choice.

**INGREDIENTS**

Capric Acid, Cholesterol, Citric Acid, Conjugated Linoleic Acid, Dimethicone, Disodium EDTA, E.

Cerifera (Candelilla) Wax, Food Starch Modified Corn Syrup Solids, Glycerin, Glyceryl Stearate, Hydroxypropyl Bispalmitamide MEA (Ceramide), Palmitic Acid, PEG-100 Stearate, Petrolatum, Phenoxyethanol, Potassium Hydroxide, Purified Water, Sorbic Acid, Squalane, Xanthan Gum.

**HOW SUPPLIED**

Emulsion SB is supplied as follows:

NDC 42546-155-90: 90 gram tube

NDC 42546-155-50: 50 gram tube

NDC 42546-155-52: Package contains two 50 gram tubes

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

Rx ONLY - Prescription Medical Device; Federal Law restricts this device to sale by or on the order of a physician.

Manufactured for:

PruGen, Inc. Pharmaceuticals

8714 E Vista Bonita Dr

Scottsdale, AZ 85255

**Emulsion SB Carton Label**

NDC 42546-155-90

Emulsion SB Topical Emulsion

Rx Only

90g

PruGen, Inc. Pharmaceuticals



## EMULSION SB

dressing, wound, drug

### Product Information

<b>Product Type</b>	PRESCRIPTION MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:42546-155
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42546-155-90	1 in 1 BOX		
1		90 g in 1 TUBE		
2	NHRIC:42546-155-50	1 in 1 BOX		
2		50 g in 1 TUBE		
3	NHRIC:42546-155-52	2 in 1 BOX		
3		50 g in 1 TUBE		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
premarket notification	K110732	05/05/2011	

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

