

PENLEN SPRAY EMULSION- dressing, wound, drug
SI Pharmaceuticals LLC

Penlen® Spray Emulsion
Penlen Spray Emulsion 90 mL (NDC 70063-100-01)
For Topical Dermatological Use only.Rx Only

DESCRIPTION

Penlen® Spray Emulsion is a water-based topical skin care emulsion that is indicated to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic and allergic contact dermatitis.

Penlen® Spray Emulsion contains natural extracts to moisturize the skin.

INDICATIONS & USAGE

As a prescription topical skin care emulsion to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic and allergic contact dermatitis.

Penlen® Spray Emulsion helps maintain a moist wound and skin environment, which is beneficial to the healing process.

CONTRAINDICATIONS

Penlen Spray Emulsion is contraindicated in persons with a known hypersensitivity to any of the components of the formulation

PRECAUTIONS

Penlen® Spray Emulsion is for external use only.

Product should not be used prior to MRI Imaging, as it contains silver nanoparticles that can cause heating during these procedures.

Penlen® Spray Emulsion does not contain sunscreen.

If the condition does not improve within 10 days, consult a physician.

If clinical signs of infection are present, appropriate treatment should be initiated; use of **Penlen® Spray Emulsion** may be continued during anti-infective therapy.

Keep this and other similar products out of the reach of children.

DIRECTIONS FOR USE

Spray a small amount of **Penlen® Spray Emulsion** in sufficient quantity to cover the affected skin area to be protected, and allow to dry. Reapply up to 4 times per day (or as needed).

INGREDIENTS

De-ionized water, copolymer, sodium hyaluronate in vegetable oils from African palms and silver nanoparticles (as a preservative).

HOW SUPPLIED

Penlen® Spray Emulsion is available in a 90 mL spray bottle.

PRESCRIPTION MEDICAL DEVICE: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

STORE AT ROOM TEMPERATURE

SHAKE WELL BEFORE USING

Distributed in the U.S.A. by:

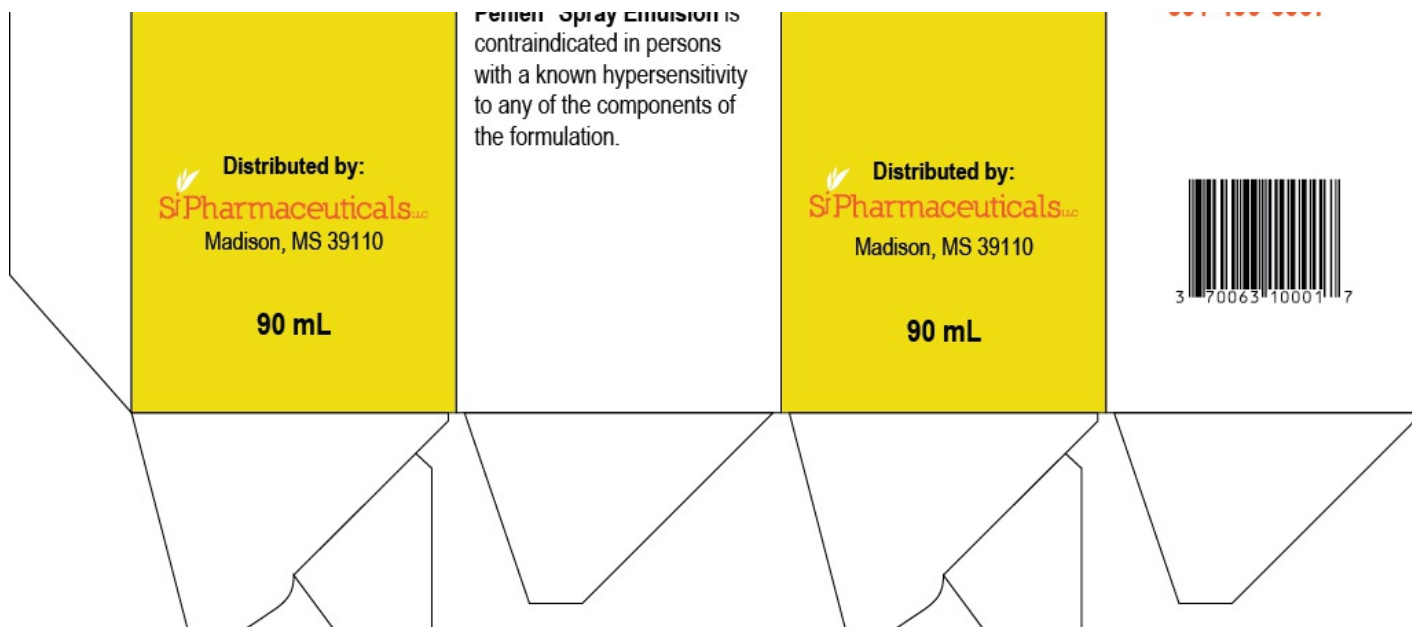
SI Pharmaceuticals LLC
Madison, MS 39110

Manufactured by: Laboratorios Zepol S.A. Costa Rica

FDA approval: K141637

Container Label





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PENLEN SPRAY EMULSION

dressing, wound, drug

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:70063-100
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:70063-100-01	1 in 1 CARTON		
1		90 mL in 1 BOTTLE, SPRAY; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K141637	12/04/2018	

Labeler - SI Pharmaceuticals LLC (079881205)