

SUVICORT RX SKIN EMULSION- dressing, wound, drug
Sterling-Knight Pharmaceuticals, LLC

SuVICORT Rx Skin Emulsion

DESCRIPTION

SuVICORT Rx Emulsion is a soothing wound gel that promotes a moist wound environment that is ideal for the healing process.

INDICATIONS & USAGE

SuVICORT Rx Skin Emulsion is indicated as a prescription topical skin care emulsion for the management of painful wounds. SuVICORT Rx Skin Emulsion helps maintain a moist wound and skin environment, which is beneficial to the healing process.

Directions: Apply a small amount of SuVICORT Rx 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).

WARNINGS

External use only. Do not use this product if you are allergic to any of the ingredients. Avoid contact with eyes. Sterile unless opened or damaged.

PRECAUTIONS:

Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

CALL YOUR DOCTOR ABOUT SIDE EFFECTS.

Call your doctor about side effects. You may report side effects to Sterling Knight Pharmaceuticals, LLC at 1-888-460-1531 or the FDA at 1-800-FDA-1088.

INSTRUCTIONS FOR USE

Apply a small amount of SuVICORT Rx 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

Water, Collagen, Aloe Vera gel, Lidocaine Hydrochloride, Sodium alginate, Glycerin, Hydroxyethylcellulose, Triethanolamine, Benzethonium chloride.

HOW SUPPLIED

SuVICORT Rx Emulsion is supplied in:

60g tube, NDC 69336-808-60

30g tube, NDC 69336-808-30

28g tube, NDC 69336-808-28

Distributed By:

Sterling-Knight Pharmaceuticals, LLC
Ripley, MS 38663
Rev 092018-1

STORAGE:

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). Protect from freezing [See USP Controlled Room Temperature].

Sterling | Knight
PHARMACEUTICALS

Rx Only

NDC 69336-808-30

Suvicort
2% Lidocaine
Rx Skin Emulsion

FORTOPICAL USE ONLY 30gr

Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

Instructions: Apply a small amount of product 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: Water, Collagen, Aloe Vera gel, Lidocaine Hydrochloride, Sodium alginate, Glycerin, Hydroxyethylcellulose, Triethanolamine, Benzethonium chloride.

Indication: Suvicort Rx Skin Emulsion is indicated 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. Suvicort Rx Skin Emulsion helps maintain a moist wound and skin environment, which is beneficial to the healing process. Suvicort Rx Skin Emulsion is contraindicated in persons with a known hypersensitivity to any of the components of the formulation.

Storage: Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). Protect from freezing [See USP Controlled Room Temperature].

Warnings: External use only. Do not use this product if you are allergic to any of the ingredients. Avoid contact with eyes. Sterile unless opened or damaged.

Manufactured for:
Sterling-Knight Pharmaceuticals, LLC | Ripley, MS 38663
Dispense in Original Container

Item 808
Rev 092018-1

N 3 69663 80830 0



RxOnly

NDC 69336-808-60

SuVICORT

2% Lidocaine

Rx Skin Emulsion

FORTOPICAL USE ONLY

60gr

Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Instructions: Apply a small amount of product 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: Water, Collagen, Aloe Vera gel, Lidocaine Hydrochloride, Sodium alginate, Glycerin, Hydroxyethylcellulose, Triethanolamine, Benzethonium chloride.

Indication: SuVICORT Rx Skin Emulsion is indicated 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. SuVICORT Rx Skin Emulsion helps maintain a moist wound and skin environment, which is beneficial to the healing process. SuVICORT Rx Skin Emulsion is contraindicated in persons with a known hypersensitivity to any of the components of the formulation.

Storage: Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). Protect from freezing [See USP Controlled Room Temperature].

Warnings: External use only. Do not use this product if you are allergic to any of the ingredients. Avoid contact with eyes. Sterile unless opened or damaged.

Manufactured for:

Sterling-Knight Pharmaceuticals, LLC | Ripley, MS 38661
Dispense in Original Container

Item 808
Rev 09/2018-1



Rx Only

Sterling | Knight
Pharmaceuticals, Inc.

NDC 69336-808-60

SuVICORT

2% Lidocaine
Rx Skin Emulsion

FORTOPICAL USE ONLY 60 gr

Indications: SuVICORT is a dermal anesthetic for the treatment of pruritus associated with psoriasis.

Warnings: SuVICORT is not intended for use on the face, scalp, or mucous membranes. Do not use on broken skin or on areas with active infection. Do not use on areas with severe sunburn, sunburn, or other skin conditions. Do not use on areas with severe allergic reactions to lidocaine or other local anesthetics. Do not use on areas with severe allergic reactions to other local anesthetics. Do not use on areas with severe allergic reactions to other local anesthetics. Do not use on areas with severe allergic reactions to other local anesthetics.

Directions: Apply SuVICORT to the affected area 15 to 30 minutes before the application of Fortopical. Do not use on areas with severe allergic reactions to lidocaine or other local anesthetics. Do not use on areas with severe allergic reactions to other local anesthetics. Do not use on areas with severe allergic reactions to other local anesthetics.

How to Use: Apply SuVICORT to the affected area 15 to 30 minutes before the application of Fortopical. Do not use on areas with severe allergic reactions to lidocaine or other local anesthetics. Do not use on areas with severe allergic reactions to other local anesthetics. Do not use on areas with severe allergic reactions to other local anesthetics.

Warnings: SuVICORT is not intended for use on the face, scalp, or mucous membranes. Do not use on broken skin or on areas with active infection. Do not use on areas with severe sunburn, sunburn, or other skin conditions. Do not use on areas with severe allergic reactions to lidocaine or other local anesthetics. Do not use on areas with severe allergic reactions to other local anesthetics. Do not use on areas with severe allergic reactions to other local anesthetics.

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How to Use: Apply SuVICORT to the affected area 15 to 30 minutes before the application of Fortopical. Do not use on areas with severe allergic reactions to lidocaine or other local anesthetics. Do not use on areas with severe allergic reactions to other local anesthetics. Do not use on areas with severe allergic reactions to other local anesthetics.

Manufacturer's Site:
Sterling | Knight Pharmaceuticals, LLC | Raleigh, NC 27605
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Lot: 19080101

Barcode: N 3 69336 80860 6

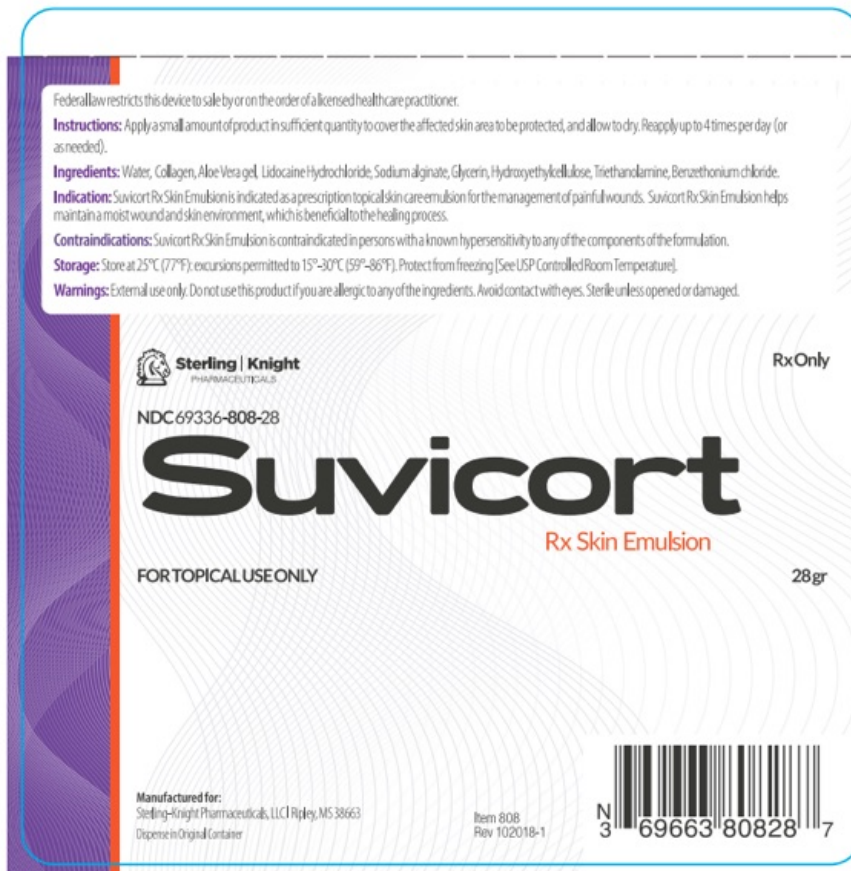
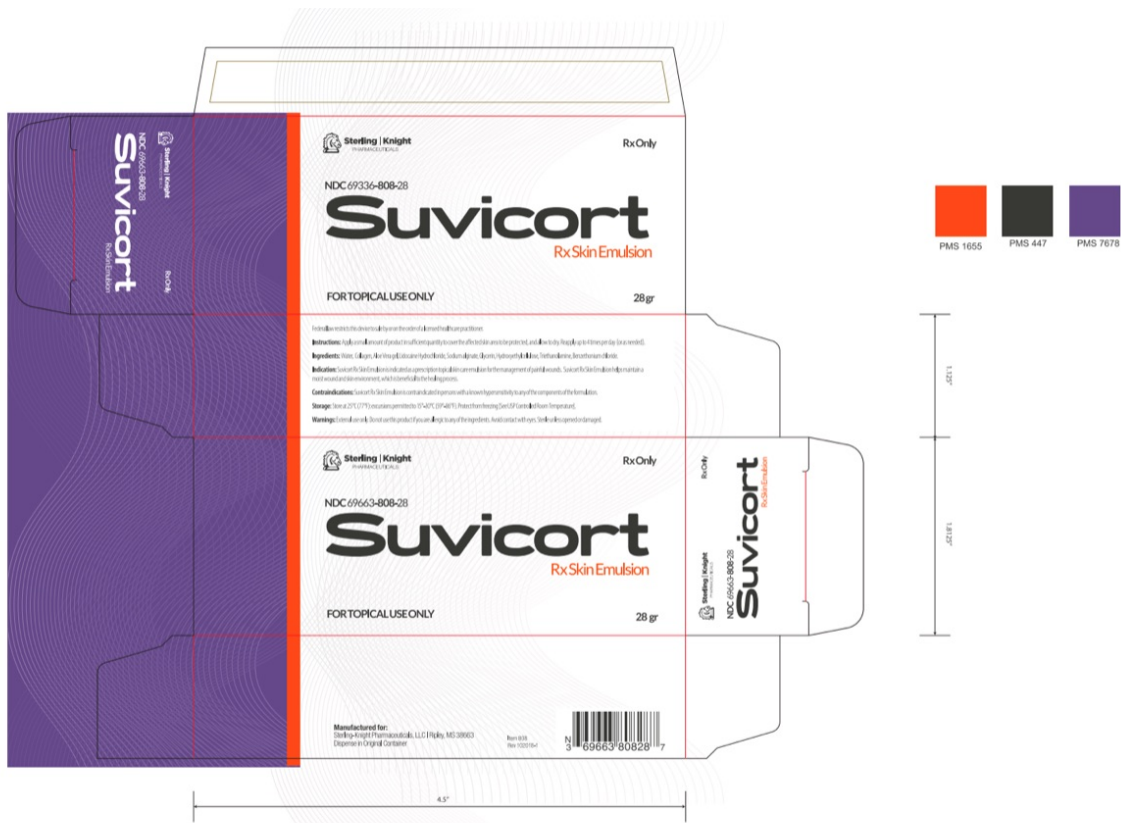
1.25" 1.25"

4.5"



Rx Only





SUVICORT RX SKIN EMULSION

dressing, wound, drug

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:69336-808
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69336-808-60	60 g in 1 TUBE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NHRIC:69336-808-30	30 g in 1 TUBE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
3	NHRIC:69336-808-28	28 g in 1 TUBE; 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	K020540	09/17/2018	

Labeler - Sterling-Knight Pharmaceuticals, LLC (079556942)

Revised: 12/2018

Sterling-Knight Pharmaceuticals, LLC