SALICYLIC ACID- salicylic acid ointment
Syntenza Pharmaceuticals LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Salicylic Acid 3% Topical Ointment

Rx Only

Prescribing Information

DESCRIPTION

Salicylic Acid 3% topical ointment contains 30 mg salicylic acid per gram in a base containing: PEG-8, PEG-75, Benzoic acid and Quercus Alba Bark Extract.

CLINICAL PHARMACOLOGY

The mechanism of action of Salicylic Acid 3% topical ointment is not known. While the following animal data are available, their clinical significance is unknown. It has been demonstrated that Salicylic Acid 3% topical ointment significantly reduces methicillin-resistant Staphylococcus aureus (MRSA) protected by biofilms in wounds using porcine models. In addition, Salicylic Acid 3% topical ointment stimulates re-epithelialization of second-degree burns in porcine models.

CLINICAL STUDIES

A randomized, double-blind, placebo-controlled study evaluated the rate of wound re-epithelialization. Four partial-thickness wounds (2×2 cm & 0.2 mm deep) were created under local anesthesia on the thighs of 13 normal, healthy, male volunteers with an electrokeratome. Salicylic Acid 3% topical ointment substantially increased the rate of re-epithelialization by 63% over the vehicle alone ($p<0.01$) and 77% over untreated control ($p<0.005$).

INDICATIONS AND USAGE

An external treatment for the inflammation and irritation associated with many common forms of dermatitis, including certain eczematoid conditions. These conditions include complications associated with pyodermas. Indicated also in the treatment of insect bites, burns and fungal infections.

CONTRAINDICATIONS

Salicylic Acid 3% topical ointment is contraindicated for use in those patients who are hypersensitive to topical polyethylene glycols.

PRECAUTIONS

For external use only. Not to be used in eyes.

DRUG INTERACTIONS

It is not known if Salicylic Acid 3% topical ointment interacts with other topical medications applied to the treatment area. The use of Salicylic Acid 3% topical ointment with other topical drugs has not been studied.

ADVERSE REACTIONS

Salicylic Acid 3% topical ointment is generally well tolerated and non-irritating. A small percentage of patients may experience a temporary burning sensation upon application of the ointment.

DOSAGE AND ADMINISTRATION

Patients should be advised to follow these step-by-step instructions for application of Salicylic Acid 3% topical ointment:

Hands should be washed thoroughly.

When using tubes, the tip of the tube should not come into contact with the area to be treated; the tube should be recapped tightly after each application.

If applying with a cotton-tipped applicator, which is recommended, use once and discard.

Salicylic Acid 3% topical ointment should be applied twice a day for best results.

Gently rinse the area to be treated with saline or water and then pat dry. Salicylic Acid 3% topical ointment can be applied directly to the wound or placed on dry gauze and then placed on the wound. Wet-Packs or Wet-To-Dry Dressings are not recommended since they will dilute the ointment and decrease its effectiveness. Salicylic Acid 3% topical ointment is designed to provide moisture to the wound.

Spread a generous quantity of Salicylic Acid 3% topical ointment evenly over the desired area to yield a thin continuous layer of approximately 1/8 of an inch of thickness. There may be a mild warming sensation, or slight burning, to the treated area for 3-5 minutes after application. If irritation occurs or symptoms persist after 10 days, discontinue use and consult your physician.

Try to keep the area being treated clean and exposed to air when possible. Apply an appropriate dressing to shield the area from clothes or exposure to water or dirt.

If there is no improvement in the wound within 7 days, consult your physician for further evaluation of the wound. If there is no response to the ointment at all, then the wound should be re-evaluated for other contributing factors to the wound healing process.

PEDIATRIC USE

Safety and effectiveness in pediatric patients has not been established.

HOW SUPPLIED

30 g tube NDC 72056-030-01

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

Manufactured for:
Syntenza Pharmaceuticals LLC
Edina, MN 55436, USA

Rev. 06/18

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

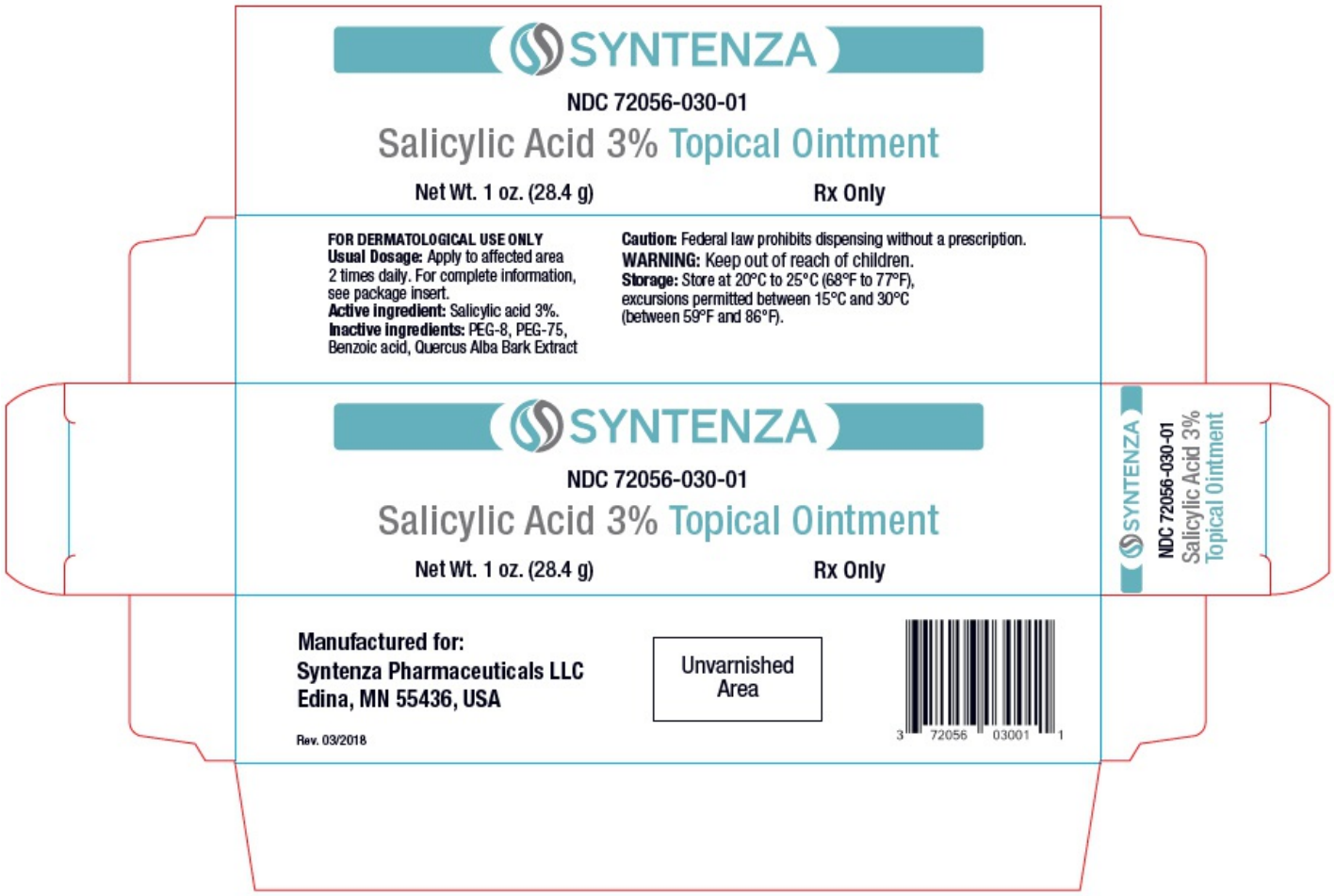
SYNTENZA

NDC 72056-030-01

Salicylic Acid 3% Topical Ointment

Net Wt. 1 oz. (28.4 g)

Rx Only



SALICYLIC ACID

salicylic acid ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72056-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Benzoic Acid (UNII: 8SKN0B0MIM)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72056-030-01	1 in 1 CARTON	10/05/2018	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		10/05/2018	

Labeler - Syntenza Pharmaceuticals LLC (080999747)

Revised: 10/2018 Syntenza Pharmaceuticals LLC