

SALICYLIC ACID- salicylic acid ointment

Trifluent Pharma 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% with Benzoic Acid and Oak Bark Extract

Rx Only

Prescribing Information

DESCRIPTION

Salicylic acid with oak bark ointment contains 30 mg salicylic acid per gram in a base containing: Benzoic acid, polyethylene glycol 400, polyethylene glycol 3350 and oak bark extract (QRB-7).

CLINICAL PHARMACOLOGY

The mechanism of action of salicylic acid with oak bark is not known. While the following animal data are available, their clinical significance is unknown. It has been demonstrated that salicylic acid with oak bark significantly reduces methicillin-resistant *Staphylococcus aureus* (MRSA) protected by biofilms in wounds using porcine models. In addition, salicylic acid with oak bark stimulates reepithelialization of second-degree burns in porcine models.

CLINICAL STUDIES

A randomized, double-blind, placebo-controlled study evaluated the rate of wound reepithelialization. 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 electro keratome. Salicylic acid with oak bark substantially increased the rate of reepithelialization 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.

CONTRADICTIONS

Salicylic acid with oak bark 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 Salicyclic acid with oak bark interacts with other topical medications applied to the treatment area. The use of salicyclic acid with oak bark with other topical drugs has not been studied.

ADVERSE REACTIONS

Salicyclic acid with oak bark 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 salicyclic acid with oak bark 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. Salicyclic acid with oak bark 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. Salicyclic acid with oak bark 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. Salicyclic acid with oak bark is designed to provide moisture to the wound.

Spread a generous quantity of salicyclic acid with oak bark 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 73352-0107-30

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.

Salicylic Acid with Oak Bark inhibited all tested microbial stains, both Gram negative and Gram positive, in a Minimum Inhibitory Concentration (MIC) test against the following 49 select pathogens.

Minimum Inhibitory Concentration Testing of QRB-7 The minimum inhibitory concentrations (MIC) of QRB-7 are listed below in parts per million (PPM)*.

Microorganism	QRB-7
<i>Microorganism</i>	<i>Parts per Million</i>
Staphylococcus aureus, ATCC 6538	25,000
Salmonella choleraesuis, ATCC 10708	25,000
*Enterococcus faecalis, ATCC 19433	50,000
Pseudomonas cepacia, ATCC 10856	3,125
Staphylococcus epidermidis, ATCC 17917	12,500
Alcaligenes faecalis, ATCC 8750	25,000
Streptococcus uberis ATCC 27958	12,500
Escherichia coli, ATCC 25922	25,000
Klebsiella pneumoniae, ATCC 13883	25,000
Pseudomonas aeruginosa, ATCC 10145	25,000
Shigella flexneri type 1A ATCC 9199	12,500
Pseudomonas paucimobilis, ATCC 29837	1,563
Streptococcus sanguis, ATCC 10556	12,500
Acinetobacter lewoffii, ATCC 9957	25,000
Pseudomonas putida, HTB Isolate	6,250
Aeromonas sobria, ATCC 9071	25,000
Staphylococcus hominus, ATCC 27844	12,500
Staphylococcus haemolyticus, ATCC 29970	25,000
Staphylococcus saprophyticus, ATCC 15305	25,000
Staphylococcus simulans, ATCC 27848	25,000
Micrococcus lylae, ATCC 27566	50,000
Streptococcus agalactiae ATCC 13813	12,500
Streptococcus equisimilis ATCC 9542	12,500

Pseudomonas alcaligenes, ATCC 14909	25,000
Klebsiella oxytoca, ATCC 15764	12,500
Pseudomonas stutzeri, ATCC 17588	50,000
Salmonella typhi, ATCC 6539	12,500
Enterobacter aerogenes, ATCC 15038	25,000
Group D enterococcus	50,000
Trichophyton mentagraphytes CDC y68+	50,000
Rhodoturula rubra HTB Isolate	50,000
Enterobacter cloacae, Hosp/Envi isolate	25,000
Escherichia coli, Hosp/Envi isolate	25,000
Pseudomonas cepacia, Hosp/Envi isolate	25,000
Klebsiella pneumoniae, Hosp/Envi isolate	25,000
Staphylococcus aureus, Hosp/Envi isolate	50,000
Acinetobacter calcoaceticus, ATCC 17961	25,000
Alcaligenes faecalis, ATCC 337	25,000
Enterobacter cloacae, ATCC 23355	25,000
Achromobacter xylosoxidans, HTB Isolate	25,000
Salmonella typhi, ATCC 19430	25,000
Listeria monocytogenes, ATCC 15313	12,500
Serratia marcesans, ATCC 14756	25,000
Serratia marcesans, ATCC 13880	25,000
Candida albicans, ATCC 10231	12,500
Serratia marcesans, Hosp/Envi isolate	25,000
Salmonella enteritidis, ATCC 13076	25,000
Escherichia coli, ATCC 11229	25,000
Proteus mirabilis, ATCC 9240	25,000

* Data on file: 7 Oaks Pharmaceutical Corp., Easley, SC

Manufactured for: Trifluent Pharma, LLC • San Antonio, TX
SAL01-02/22

PRINCIPAL DISPLAY PANEL - 30 gram Tube Label

Topical Ointment
NDC 73352-0107-30

Salicylic Acid 3%
with Benzoic Acid and Oak Bark Extract

Rx only
TRIFLUENT
PHARMA
Net wt. 30 grams

Topical Ointment

NDC 73352-0107-30

6x1mm

Salicylic Acid 3%

with Benzoic Acid and Oak Bark Extract

R_x only



Net wt. 30 grams

FOR DERMATOLOGICAL USE ONLY

Usual Dosage: Apply to affected area 2 times daily. For complete information, see package insert.

Active ingredient: Salicylic acid 3%.

Inactive ingredients: Benzoic acid, Polyethylene glycol 400, Polyethylene glycol 3350, Oak Bark Extract (QRB7)

Caution: Federal law prohibits dispensing without a prescription.

Warning: Keep out of reach of children.

Storage: 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).

Manufactured for: Trifluent Pharma, San Antonio, TX 78213

Rev. 01/2022

6x3mm

SALICYLIC ACID

salicylic acid ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:73352-107
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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73352-107-30	1 in 1 CARTON	02/15/2022	
1		30 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		02/15/2022	07/01/2025

Labeler - Trifluent Pharma LLC (117167281)

Establishment

Name	Address	ID/FEI	Business Operations
Dynamic Pharmaceuticals		617660712	MANUFACTURE(73352-107)

Revised: 1/2024

Trifluent Pharma LLC