BENSAL HP- salicylic acid ointment
SMG 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.

Bensal^{HP} ®
TOPICAL OINTMENT

Rx Only

Prescribing Information

DESCRIPTION

Bensal HP ® 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 Bensal HP® is not known. While the following animal data are available, their clinical significance is unknown. It has been demonstrated that Bensal HP® significantly reduces methicillin-resistant Staphylococcus aureus (MRSA) protected by biofilms in wounds using porcine models. In addition, Bensal HP® 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. Bensal HP® 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

Bensal HP® 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 Bensal HP® interacts with other topical medications applied to the treatment area. The use of Bensal HP® with other topical drugs has not been studied.

ADVERSE REACTIONS

Bensal HP® 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 Bensal HP® 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.

Bensal HP® 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. Bensal HP® 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. Bensal HP® is designed to provide moisture to the wound.

Spread a generous quantity of Bensal HP® 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 63801 - 0107 - 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.

Bensal HP® inhibited all tested microbial strains, 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**
Microorganism	*Parts Per Million*
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, ATC 25922	25,000
Klebsiella pneumoniae, ATCC 13883	25,000
Pseudomonas aeruginosa, ATCC 10145	25,000
Shigella flexneri type 1A ATTC 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 mentagrophytes CDC y68+	50,000
Rhodotorula 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 marcensans, 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: **EPI Health, LLC** • Charleston, SC 29403

For: **7 Oaks Pharmaceutical Corp.** • Easley, SC • 877.723.6725

BHP-PI TD 0517

PRINCIPAL DISPLAY PANEL - 30 gram Tube Carton

Topical Ointment
NDC 63801-0107-01

Bensal HP ®

Rx only
Net wt. 30 grams

BENSAL HP
salicylic acid ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63801-107
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

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
QUERCUS RUBRA BARK (UNII: X26K8566JX)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63801-107-01	1 in 1 CARTON	10/01/1998	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:63801-107-15	2 g in 1 TUBE; Type 0: Not a Combination Product	10/01/1998	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/01/1998	

Labeler - SMG Pharmaceuticals, LLC (079332298)

Establishment

Name	Address	ID/FEI	Business Operations
Dynamic Pharmaceuticals		617660712	MANUFACTURE(63801-107)

Revised: 1/2023 SMG Pharmaceuticals, LLC