DEBACTEROL CANKER SORE PAIN RELIEF- phenolsulfonic acid and sulfuric acid solution
EPIEN Medical Inc
Reference Label Set Id: 22b16c69-598a-432b-aa23-971b4e9e7ad5

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.

DEBACTEROL Canker Sore Pain Relief

Debacterol is a dark brown, semi-viscous liquid. It contains sulfonated phenolics and sulfuric acid, which are tissue denaturants, in an aqueous solution.

Contains 50% Sulfonated phenolics and 30% sulfuric acid in an aqueous solution.

Debacterol is indicated in the topical treatment of ulcerating lesions of the oral cavity such as Recurrent Aphthous Stomatitis (Canker Sores). Debacterol provides relief from the pain and discomfort of oral mucosal ulcers. **Debacterol is not intended for the treatment of vesicular lesions, such as Cold Sores or Fever Blisters**.

Immediately before applying Debacterol **thoroughly dry** the ulcerated area of oral mucosa that is to be treated using a cotton-tipped applicator, or by usiing some similar method.

For Swab:

After drying the lesion, hold the Debacterol applicator swab with the colored ring end up. Bend the colored ring tip gently to the side until it "snaps" to release the liquid inside. Liquid flows down into the white cotton tip applicator. Apply the Debacterol - coated applicator tip to the dried ulcer area for at least **5 seconds.**

For Vial:

After drying the lesion, dip the tip of a cotton tipped applicator into the Debacterol, until it is coated with sufficient agent to coat the entire ulcerated area. Apply the Debacterol - coated applicator tip to the dried ulcer area for at least **5 seconds.**

Use a rolling motion to completely cover the entire ulcer bed and ulcer rim. A "stinging" sensation is experienced immediately upon application of the Debacterol to the ulcer. Do not hold the applicator on the ulcer for more than 10 seconds. Debactorol will not harm the normal oral mucosa when used as directed. **Thoroughly rinse out the mouth with water and spit out the rinse water**. The stinging sensation and ulcer pain will subside almost immediately after the water rinse. One application per ulcer treatment is usually sufficient. However, if the ulcer pain returns shortly after rinsing with water, it is an indication that some part of the ulcer was not covered. Repeat application one more time following the directions above.

It is not recommended that more than one treatment session be performed on an individual mucosal ulcer.

Keep out of reach of children. Do not use if allergic to a material that contains sulfur in any form. Because of its nature, prolonged use of Debacterol on normal tissue should be avoided. Debacterol will eventually necrotize and slough all tissue to which it is applied sufficient volume and should be applied carefully. Debacterol may be harmful with swallowed. If ingested do not induce vomiting. Immediately get medical help or contact a Poison Control Center. If eye exposure occurs, immediately remove any contact lenses and irrigate eyes for at least 15 minutes with lukewarm water and contact a physician.

Debacterol is for use in the oral cavity only. Avoid eye contact. Saftey and effectiveness in pregnant women and children under the age of 12 has not been established.

Debacterol may cause local irritation upon administration. If excess irritation occurs during use, a rinse

with sodium bicarbonate (baking soda) solution will neutralize the reaction (use 0.5 teaspoon in 120ml of water). If condition persists contact a health care professional.

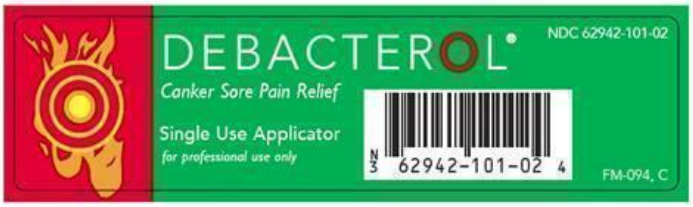
Swab contains 0.2 ml of product. (NDC-62942-101-02)

Vial contains 1.5 ml of product. (NDC-62942-101-03)

Store at room temperature, 15°C-30°C or 59°F-86°F.

Principal Display Panel - DEBACTEROL SINGLE USE APPLICATOR FRONT LABEL

Debacterol Single Use Applicator - DEBACTEROL SINGLE USE APPLICATOR FRONT LABEL

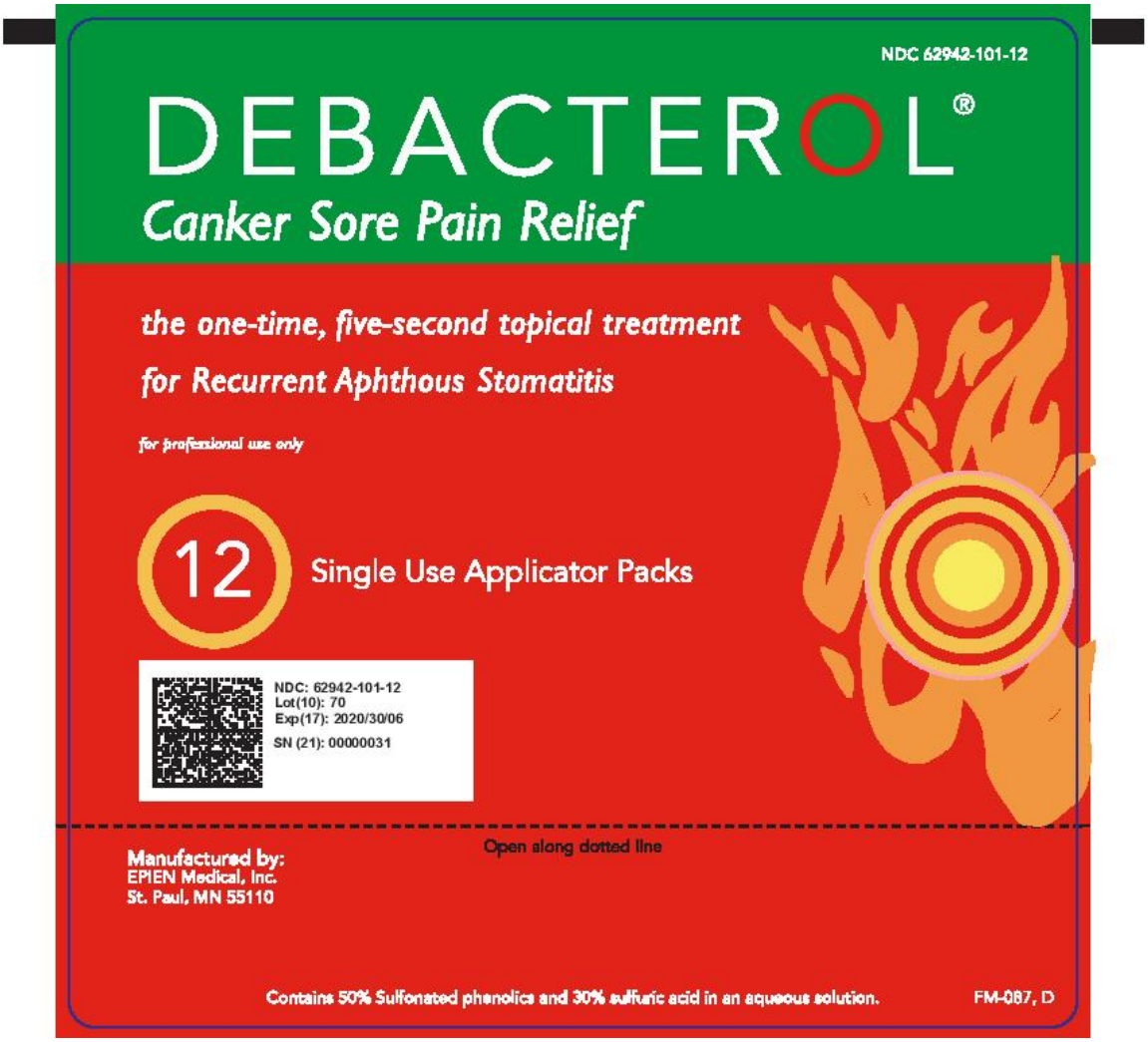


FRONT LABEL

Principal Display Panel - DEBACTEROL SINGLE USE APPLICATOR BACK LABEL

DEBACTEROL SINGLE USE - DEBACTEROL SINGLE USE APPLICATOR BACK LABEL

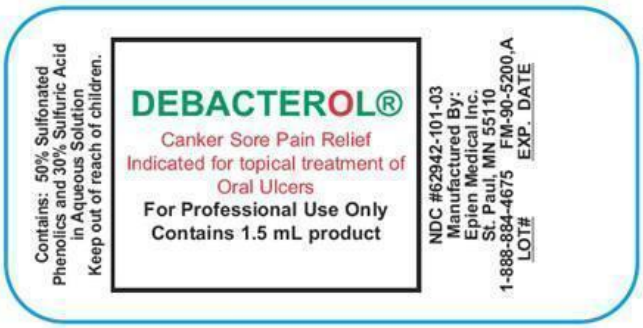
PRINCIPAL DISPLAY PANEL - DEBACTEROL 12 PACK LABEL



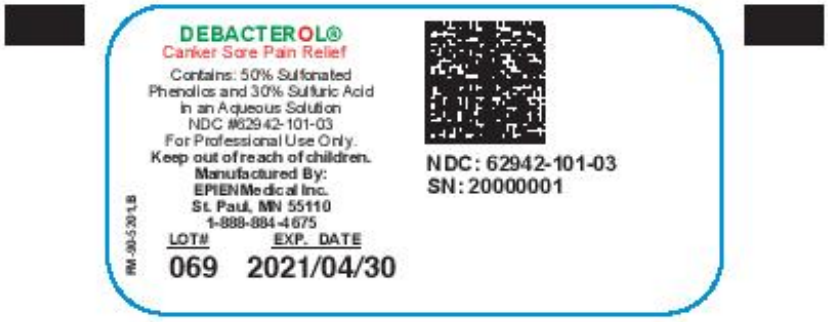
DEBACTEROL 12 PACK LABEL

PRINCIPAL DISPLAY PANEL - DEBACTEROL VIAL LABEL

DEBACTEROL VIAL LABEL



PRINCIPAL DISPLAY PANEL - DEBACTEROL VIAL BOX LABEL



DEBACTEROL CANKER SORE PAIN RELIEF

phenolsulfonic acid and sulfuric acid solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62942-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENOLSULFONIC ACID (UNII: L74LRO149A) (PHENOLSULFONIC ACID - UNII:L74LRO149A)	PHENOLSULFONIC ACID	0.5 g in 1 mL
SULFURIC ACID (UNII: O40UQP6WCF) (SULFURIC ACID - UNII:O40UQP6WCF)	SULFURIC ACID	0.3 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	0.2 g in 1 mL

Product Characteristics

Color	brown (Dark)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62942-101-12	12 in 1 BOX	09/01/1996	
1	NDC:62942-101-02	0.2 mL in 1 APPLICATOR; Type 6: Drug/Biologic Combination		
2	NDC:62942-101-03	1 in 1 BOX	09/01/1996	
2		1.5 mL in 1 VIAL, GLASS; Type 6: Drug/Biologic Combination		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/01/1996	

Labeler - EPIEN Medical Inc (128678765)

Establishment

Name	Address	ID/FEI	Business Operations
EPIEN Medical Inc		128678765	manufacture(62942-101)

Revised: 12/2020 EPIEN Medical Inc