

## DEBACTEROL®

Canker Sore Pain Relief  
the one-time, five-second topical  
treatment for Oral Ulcers

### INSTRUCTIONS FOR USE

for professional use only

**INDICATIONS:** 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.**

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

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

directly to the dried ulcer bed 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. Debacterol® will not harm the normal oral mucosa when used as directed. **Thoroughly rinse out 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.**

**WARNINGS:** 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 in sufficient volume and should be applied

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carefully. Debacterol® may be harmful if 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.

**PRECAUTIONS:** General – Debacterol® is for use in the oral cavity only. Avoid eye contact. Safety and effectiveness in pregnant women and children under the age of 12 has not been established.

**ADVERSE REACTIONS:** 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 120 mL of water). If condition persists contact a health care professional.

**HOW SUPPLIED:** 1.5mL of product in a glass container Store at room temperature 15°-30°C or 59°-86°F. (NDC 62942-101-03)

**CONTAINS:** 50% Sulfonated phenolics and 30% sulfuric acid in an aqueous solution.

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Manufactured By:  
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Client: Epien Medical, INC. Proof Date: 06-24-20  
Job Number: 27951 Proof Number: 1  
Part Number/Description: FM-90-4200,B  
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