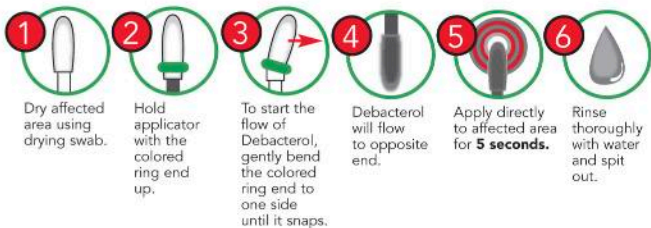


## Instructions for use for professional use only



**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, hold 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 tip applicator. 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. Debacterol® 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.**

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

**How supplied:** Swab contains 0.20 mL of product. Store at room temperature, 15°C-30°C or 59°F-86°F.

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

**Federal Law prohibits dispensing without a prescription.**

### Manufactured By:

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and patent pending.