



Rx Only

NDC 16781-113-60

Use As Directed.

Not for ophthalmic use.

Active Ingredients:

Benzocaine 14.0% w/w, Butamben 2.0% w/w, Tetracaine Hydrochloride 2.0% w/w
(Percentages refer to concentrate and exclude propellant)

Contains: Benzalkonium Chloride, Cetyldimethylethylammonium bromide, Dipropylene Glycol, Flavoring (Cherry), Saccharin. Also Contains: Propellant HFA-134a (1,1,1,2-tetrafluoroethane).

Action: The onset of Exactacain produced anesthesia is rapid (approximately 30 seconds) and the duration of anesthesia is typically 30-60 minutes, when used as directed. The effect is due to the rapid onset, but short duration of action of Benzocaine coupled with the slow onset, but extended duration of Tetracaine HCl and bridged by the intermediate action of Butamben.

It is believed that all of these agents act by reversibly blocking nerve conduction. Speed and duration of action is determined by the ability of the agent to be absorbed by the mucous membrane and nerve sheath and then to diffuse out, and ultimately be metabolized (primarily by plasma cholinesterases) to inert metabolites which are excreted in the urine.

Indications: Exactacain is a topical anesthetic indicated for the production of anesthesia of all accessible mucous membrane except the eyes. Exactacain is indicated for use to control pain or gagging. Exactacain is indicated for use to control pain and for use for surgical and endoscopic or other procedures in the ear, nose, mouth, pharynx, larynx, trachea, bronchi, and esophagus. It may also be used for vaginal or rectal procedures when feasible.

Dosage and Administration: Apply 3 metered sprays of Exactacain for normal anesthesia. **Dosing in excess of 6 metered sprays is contraindicated.** Tissue need not be dried prior to application of Exactacain. Exactacain should be applied directly to the site where pain control is required.

Adverse Reactions: *Hypersensitivity Reactions:* Unpredictable adverse reactions (i.e. hypersensitivity, including anaphylaxis) are extremely rare.

Localized allergic reactions may occur after prolonged or repeated use of any aminobenzoate anesthetic. The most common adverse reaction caused by local anesthetics is contact dermatitis characterized by erythema and pruritus that may progress to vesiculation and oozing. This occurs most commonly in patients following prolonged self-medication, which is contraindicated. If rash, urticaria, edema or other manifestations of allergy develop during use, the drug should be discontinued. To minimize the possibility of a serious allergic reaction, Exactacain preparation should not be applied for prolonged periods except under continual supervision. Dehydration of the epithelium or an escharotic effect may also result from prolonged contact.

Precaution: On rare occasions, methemoglobinemia has been reported in connection with the use of products containing Benzocaine and related compounds. **Care should be used not to exceed 6 metered sprays.** If a patient becomes cyanotic, treat appropriately to counteract (such as with methylene blue, if medically indicated).

Use in Pregnancy: Safe use of Exactacain has not been established with respect to possible adverse effects upon fetal development. Therefore, Exactacain should not be used during early pregnancy, unless in the judgment of a physician, the potential benefits outweigh the unknown hazards. Routine precaution for the use of any topical anesthetic should be observed when Exactacain is used.

Use in pediatric and geriatric populations: Appropriate pediatric and geriatric dosage has not been established for this product. Dosage should be reduced in the debilitated elderly, acutely ill, very young patients or others with conditions resulting in a greater risk from methemoglobinemia.

Contraindications: Exactacain is not suitable and should never be used for injection. Do not use on the eyes. To avoid excessive systemic absorption, Exactacain should not be applied to large areas of denuded or inflamed tissue. Exactacain should not be administered to patients who are hypersensitive to any of its ingredients or to patients known to have cholinesterase deficiencies. Tolerance may vary with the status of the patient. Dosage should be reduced in the debilitated elderly, acutely ill, very young patients or others with conditions resulting in a greater risk from methemoglobinemia.

Individual dosage of tetracaine hydrochloride in excess of 6 metered sprays is contraindicated. Exactacain should not be used under dentures or cotton rolls, as retention of the active ingredients under a denture or cotton roll could possible cause an escharotic effect. Routine precaution for the use of any topical anesthetic should be observed when using Exactacain.

Disposable Applicators for Exactacain Spray:

- The 5" Exactacain disposable, single-use applicators are designed for accessibility and application of Exactacain, at the required site of pain control
- A disposable applicator is inserted firmly into the spray nozzle on the can of Exactacain
- The disposable applicator should be discarded after each patient use and a new disposable applicator inserted prior to the next use of the product

How Supplied: Exactacain is available in a 60 g can (including propellant) NDC 16781-113-60, packaged with 100 disposable applicators. Additional disposable applicators are available (order number 16781-113-00).

Contents Under Pressure: Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 120°F may cause bursting. Never throw container into fire or incinerator. Keep out of reach of children. DO NOT spray in eyes.

Store at controlled room temperature, 20°C-25°C (68°F - 77°F). The canister should be at room temperature before use.

Marketed by:



Onset Therapeutics
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Reorder No:
Exactacain Spray 16781-113-60
Additional Disposable Applicators: 16781-113-00

P/N: 2601 Rev. 0
Revision Date: 9/08

Exactacain is a trademark of Onset Therapeutics

Patent Pending