ONE TOUCH ADVANCED TOPICAL ANESTHETIC BUBBLE GUM- benzocaine, butamben, tetracaine hydrochloride gel
HAGER WORLDWIDE, INC.

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.

OneTouch
Advanced

Topical Anesthetic Gel

Rx Only

Active Ingredients:	
Benzocaine	14.0%
Butamben	2.0%
Tetracaine Hydrochloride	2.0%

Inactive Ingredients:

Benzalkonium chloride	0.5%
Cetyl Dimethyl Ethyl Ammonium Bromide	0.005%
In bland, water-soluble base.	

Action
The onset of OneTouch Advanced-produced anesthesia is rapid (approximately 30 seconds) and the duration of anesthesia is typically 30-60 minutes, when used as directed. This effect is due to the rapid onset, but short duration of action of Benzocaine coupled with the slow onset, but extended duration of Tetracaine HCI 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
OneTouch Advanced Gel is a topical anesthetic indicated for the production of anesthesia of all accessible mucous membrane except the eyes. OneTouch Advanced Gel is indicated for use to control pain in the mouth.

Dosage and Administration
Only a limited quantity is OneTouch Advanced Gel is required for anesthesia.

Dispense 200 mg of gel (a bead approximately 1/4 to 1/2 inches long) by gently depressing the pump. Dispensing a bead of gel in excess of 400 mg is contraindicated. Spread thinly and evenly over the desired area using a cotton swab.

An appropriate pediatric dosage has not been established for OneTouch Advanced Gel.

Dosages should be reduced in the debilitated elderly, acutely ill, and very young patients.

Tissue need not be dried prior to application of OneTouch Advanced Gel. One-Touch Advanced Gel should be applied directly to the site where pain control is required. Anesthesia is produced within one minute with an approximate duration of thirty minutes. Each 200 mg dose of OneTouch Advanced Gel contains 28 mg of benzocaine, 4 mg of butamben and 4 mg of tetracaine HCI.

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, OneTouch Advanced Gel 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 benzocaine-containing products. Care should be used not to exceed the maximum recommended dosage (see Dosage and Administration). If a patient becomes cyanotic, treat appropriately to counteract (such as with methylene blue, if medically indicated).

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

Contraindications

OneTouch Advanced Gel is not suitable and should never be used for injection. Do not use on the eyes. To avoid excessive systemic absorption, OneTouch Advanced Gel should not be applied to large areas of denuded or inflamed tissue. OneTouch Advanced Gel 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 status of the patient.

OneTouch Advanced Gel should not be used under dentures or cotton rolls, as retention of the active gel ingredients under a denture or cotton roll could possibly cause an escharotic effect. Routine precaution for the use of any topical anesthetic should be observed when using OneTouch Advanced Gel.

How-Supplied

OneTouch Advanced Gel, 32 g jar

Cool Mint	NDC 62565-901-01
Strawberry Ice	NDC 62565-902-01

Bubble Gum	NDC 62565-903-01
Cherry	NDC 62565-904-01

Manufactured for
HAGER
WORLDWIDE
13322 Byrd Drive
Odessa, FL 33556 USA

Made in U.S.A. Rev. 6/09

Caution: Rx Only.
Do not use in eyes. Keep out of reach of children.

Directions: Read package insert.
Press top of container to dispense desired amount.
Dispense 200 mg of gel (a bead approximately 1/4 to 1/2 inches long) by gently depressing the pump. Dispensing a bead in excess of 400 mg is contraindicated. Spread thinly and evenly over the desired area using a cotton swab.

Active Ingredients: Benzocaine 14.0%, Butamben 2.0%, Tetracaine Hydrochloride 2.0%
Inactive Ingredients: Benzalkonium Chloride 0.5%, Cetyl Dimethyl Ethyl Ammonium Bromide 0.005%, in a bland water-soluble base.

NDC 62565-903-01
OneTouch
Advanced

Topical Anesthetic Gel
OneTouch Advanced is indicated for anesthesia of accessible mucous membrane.

Bubble Gum
Net Wt. 32 g

Store in a cool dry place.

Manufactured for:
HAGER
WORLDWIDE
Odessa, FL 33556 USA

Item #6256590301

Made in U.S.A. Rev. 05/09

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benzocaine, butamben, tetracaine hydrochloride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62565-903
Route of Administration	TOPICAL, DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	28 mg in .2 g
BUTAMBEN (UNII: EFW857872Q) (BUTAMBEN - UNII:EFW857872Q)	BUTAMBEN	4 mg in .2 g
TETRACAINE HYDROCHLORIDE (UNII: 5NF5D4OPCI) (TETRACAINE - UNII:0619F35CGV)	TETRACAINE HYDROCHLORIDE	4 mg in .2 g

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	1 mg in .2 g

Product Characteristics			
Color	purple (PURPLE)	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM (BUBBLE GUM)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62565-903-01	1 in 1 BOX		
1		32 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/01/2009	

Labeler - HAGER WORLDWIDE, INC. (009277971)

Registrant - HAGER WORLDWIDE, INC. (009277971)

Establishment

Name	Address	ID/FEI	Business Operations
HAGER WORLDWIDE, INC.		009277971	manufacture

Revised: 11/2011 HAGER WORLDWIDE, INC.