ONETOUCH REVOLUTION TOPICAL ANESTHETIC- benzocaine gel
HAGER WORLDWIDE, INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

OneTouch Revolution Topical Anesthetic Gel Strawberry Ice Flavor

Active ingridients (in each gram)

Benzocaine 20%

Purpose

Oral Anesthetic

Use

Temporary relief of minor toothache, pain and sore mouth associated with canker sores, dentures and orthodontic devices

Warnings

Methemoglobinemia warning:

Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if they or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Do not exceed reccommended dosage

Do not use if you have a history of allergies to local anesthetics such as procaine, butacaine, benzocaine or other ‘caine’ anesthetics

Do not use for more than 7 days unless directed by a doctor or dentist

Stop using and ask a doctor if swelling, rash or fever develops or if irritation, pain or redness persists of gets worse

Do not exceed recommended dosage.

Keep out of reach of children. In case of overdose, get medical help or Contact Poison Control Center right away

Do not use

- for teething
- in children under 2 years of age

Directions

Adults and children 12 years and over. Press top of container and dispense 0.2 mL. Apply 0.2 mL of gel to the desired area using a cotton swab.

Children under 12 should be supervised by an adult.

Children under 2 years of age, consult a doctor.

Other information

Store at room temperature
20˚-25˚ C (68˚ - 77˚ F).

Protect from freezing.

Inactive ingredients

Propylene glycol, polyethylene glycol, carbomer, sodium saccharin, povidone, flavoring and FD&C Red No. 40.

Questions or comments

Contact Hager Worldwide at (800) 328-2335

PRINCIPAL DISPLAY PANEL - Jar Label

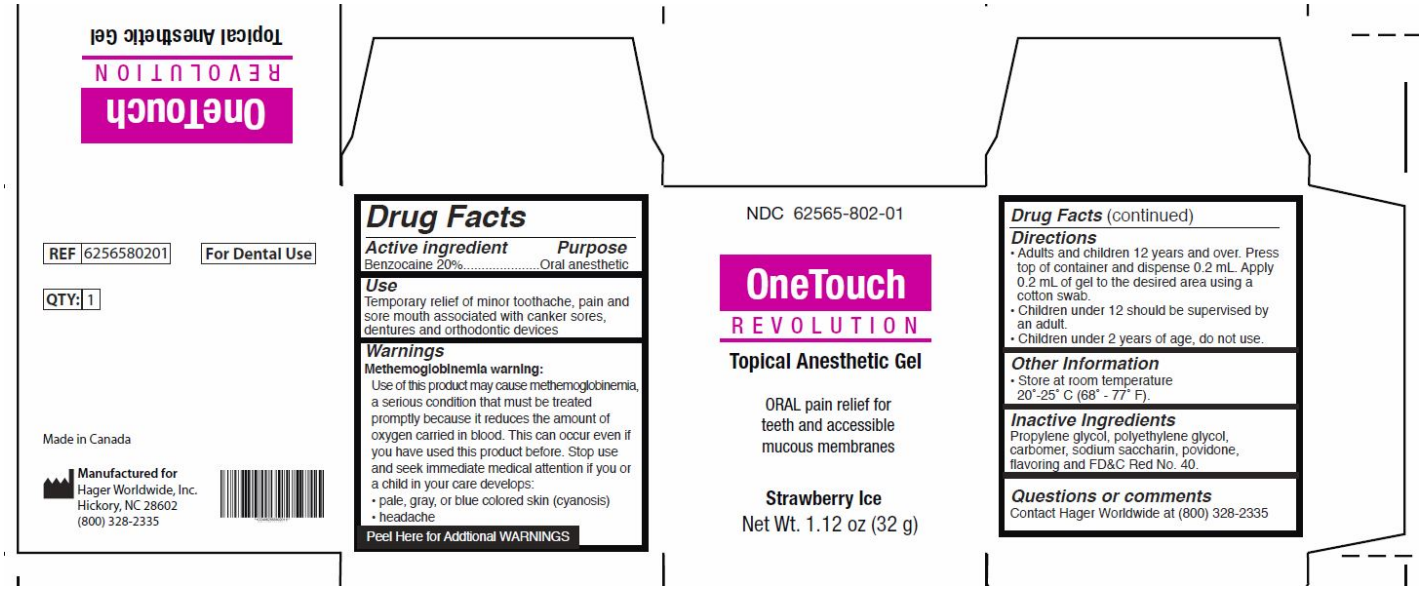
NDC 62565-802-01
OneTouch
Revolution

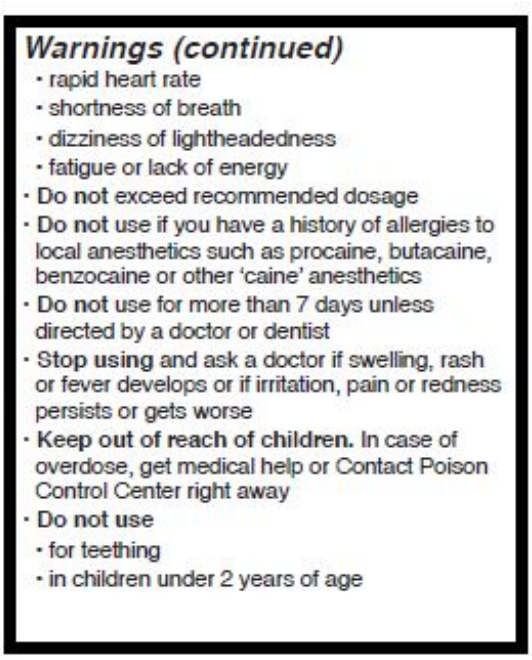
Topical Anesthetic Gel

OneTouch Revolution is indicated for anesthesia of accessible mucous membrane.

Strawberry Ice

Net Wt. 1.12 oz (32 g)





ONETOUCH REVOLUTION TOPICAL ANESTHETIC

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62565-802
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	200 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics			
Color	RED	**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62565-802-01	32 g in 1 JAR; Type 0: Not a Combination Product	05/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	05/05/2017	

Labeler - HAGER WORLDWIDE, INC. (009277971)

Registrant - HAGER WORLDWIDE, INC. (009277971)

Revised: 7/2018 HAGER WORLDWIDE, INC.