

**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 Cool Mint Flavor

Active ingredients (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 recommended 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 or 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, ethyl alcohol, methylparaben, propyl paraben, flavoring, D&C Yellow No. 10 and FD&C Blue No. 1.

Questions or comments

Contact Hager Worldwide at (800) 328-2335

PRINCIPAL DISPLAY PANEL - Jar Label

NDC 62565-801-01

**OneTouch
Revolution**

Topical Anesthetic Gel

ORAL pain relief for teeth and accessible mucous membrane.

Cool Mint

Net Wt. 1.12 oz (32 g)

Topical Anesthetic Gel
OneTouch
 REVOLUTION

REF 6256580101

For Dental Use

QTY: 1

Made in Canada

Manufactured for
 Hager Worldwide, Inc.
 Hickory, NC 28602
 (800) 328-2335



Drug Facts

Active ingredient Purpose
 Benzocaine 20% Oral anesthetic

Use
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Peel Here for Additional WARNINGS

NDC 62565-801-01

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 REVOLUTION
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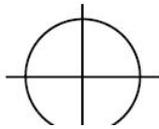
Drug Facts (continued)

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ONETOUCH REVOLUTION TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62565-801
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: 0A5MMB07FC)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62565-801-01	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)