

ORAL B INSTANT PAIN RELIEF - benzocaine gel
Health-Tech, 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.

Drug Facts

Active Ingredient

Benzocaine 20%

Purpose

Oral anesthetic

Uses

Temporarily relieves pain associated with the following mouth and gum irritations:

- toothache
- sore gums
- canker sores
- braces
- minor dental procedures
- dentures

Warnings

Allergy Alert: do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.

When using this product

- Avoid contact with eyes
- Do not exceed recommended dosage
- Do not use for more than 7 days unless directed by a doctor/dentist

Stop use and ask a doctor if:

- sore mouth symptoms do not improve in 7 days
- Irritation, pain or redness persist or worsens
- Swelling, pain or fever develops

Directions:

- Remove cap-, squeeze gel onto applicator
- Adults and children 2 years of age and older, apply to the affected area 4 times per day or as directed by a doctor/dentist
- Children under 2 years of age; consult a doctor/dentist

For Denture wearers

- Remove Dentures
- Apply thin layer to affected area

- Do not reinsert dental work until irritation is relieved
- Rinse mouth well before reinserting dentures

Other information:

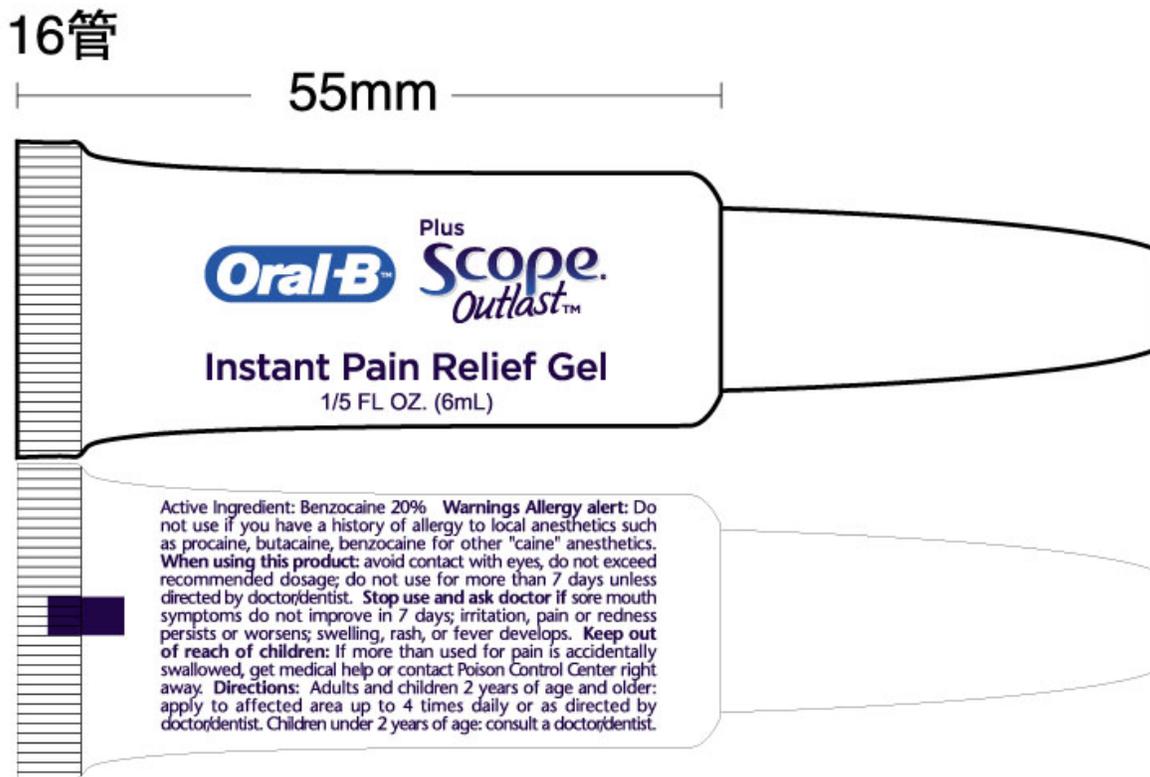
- Store between 20⁰ to 25⁰ C (68⁰ to 77⁰ F) Do not refrigerate
- Do not purchase if package has been opened

Inactive Ingredients

Benzyl alcohol, carbomer 974P, FD and C green 5, Flavor, glycerin, Methylparaben, Polyethylene glycol, PEG 400, PEG 600, Sodium Saccharin

Oral B Pain gel label

MM27



Oral B pain gel blister

MM28



PLUS
**Scope
Outlast™**
LONG LASTING MINT FLAVOR
BENZOCAINE 20%

INSTANT PAIN RELIEF GEL
MAXIMUM STRENGTH • ORAL ANESTHETIC

TOOTHACHES • GUM PAIN • CANKER SORES • DENTURE PAIN

On The Go



Three (6 mL each) Portable Applicators



**Scope
Outlast™**

INSTANT PAIN RELIEF GEL

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When using this product: ■ avoid contact with eyes ■ Do not exceed recommended dosage ■ Do not use for more than 7 days unless directed by a doctor/dentist
Stop use and ask a doctor if: ■ Sore mouth symptoms do not improve in 7 days ■ Irritation, pain or redness persists or worsens ■ Swelling, pain or fever develops.
Keep out of the reach of children. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions
■ Remove cap, squeeze gel onto applicator
■ Adults and children 2 years of age and older, apply to the affected area 4 times per day or as directed by a doctor/dentist
■ Children under 2 years of age, consult a doctor/dentist
For Denture wearers:
■ Apply thin layer to affected area
■ Do not reinsert dental work until irritation is relieved
■ Rinse mouth well before reinserting
Other information:
■ Store between 20° to 25° C (68° to 77° F) Do not refrigerate
■ Do not purchase if package has been opened

Inactive ingredients
Benzyl alcohol, carbomer 974P, FD&C Green #5, Flavor, Glycerin, Methylparaben, Polyethylene glycol, PEG 400, PEG 600, Sodium Saccharin.

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Questions? Comments? Call toll-free 1-800-600-2861 NDC 48871-008-01

Oral B shipper label

HEALTH TECH, INC
 3622 QUANTUM BLVD
 BOYNTON BEACH, FL
 33426 800-600-2861

ORAL B INSTANT PAIN RELIEF GEL

CASE PACK 12/6 ITEM: 4216 NDC 48871-008-01
 CASE QTY



00075595700901

MM29

ORAL B INSTANT PAIN RELIEF

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48871-008
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (benzocaine - UNII:U3RSY48JW5)	Benzocaine	0.2 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
benzyl alcohol (UNII: LKG8494WBH)	
Glycerin (UNII: PDC6A3C0OX)	
methylparaben (UNII: A2I8C7HI9T)	
Polyethylene glycol (UNII: 3WJQ0SDW1A)	
Polyethylene glycol 400 (UNII: B697894SGQ)	
Polyethylene Glycol 600 (UNII: NL4J9F21N9)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: K61870Z308)	

Product Characteristics

Color	green (FD and C Green 5)	Score	
Shape		Size	
Flavor	MINT (Scope Original Mint Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48871-008-01	12 in 1 BOX		
1		6 in 1 CARTON		
1		3 in 1 BLISTER PACK		
1		6 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	06/31/2010	

Labeler - Health-Tech, Inc. (084007889)

Establishment

Name	Address	ID/FEI	Business Operations
Health-Tech, Inc.		084007889	manufacture

Revised: 5/2010

Health-Tech, Inc.