7 SELECT ORAL PAIN MAXIMUM STRENGTH RELIEF- benzocaine gel 7-ELEVEN, 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.

7 Select Oral Pain Reliever Max. Strength Gel 0.5oz (58853)

Active ingredient

Purpose

Benzocaine 20%......Oral Pain reliever

Use for the temporary relief of pain due to:

- toothache
- canker sores
- gum pain
- denture pain
- cheek bites

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a 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 meddical attention if you 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

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

Do not use

- more than directed
- for more than 7 days unless directed by a dentist or doctor
- for teething
- in children under 2 years of age

Stop use and ask a doctor if

- sore mouth symptoms do not improve in 7 days
- swelling, rash or fever develops
- irritation, pain or redness persists or worsens

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222)

right away.

Directions

Adults and	Remove cap and cut tip of tube. Apply a small amount of product to
children 2 years	the cavity and around gum surrounding the teeth. Use up to 4 times
of age and older.	daily or as directed by a dentist or dentist.
Children under 12 years of age.	Should be supervised in the use of this product.
Children under 2 years of age.	Do not use.

Other information

- store at 20° to 25°C (68° to 77°F)
- this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist or doctor can be consulted
- do not use continuously

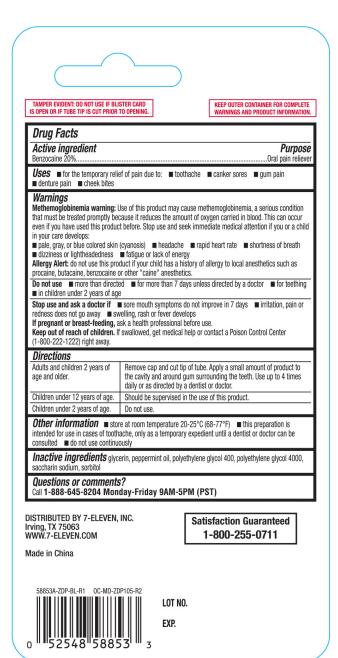
Inactive ingredients glycerin, peppermint oil, polyethylene glycol 400, polyethylene glycol 4000, saccharin sodium, sorbitol

DISTRIBUTED BY 7-ELEVEN, INC.

Irving, TX 75063

WWW.7-ELEVEN.COM





7 SELECT ORAL PAIN MAXIMUM STRENGTH RELIEF

benzocaine gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10202-853

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

BENZOCAINE (UNII: U3RSY48|W5) (BENZOCAINE - UNII:U3RSY48|W5)

BENZOCAINE

BENZOCAINE

BENZOCAINE

200 mg in 1 g

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
MINT (UNII: FV98Z8GITP)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SORBITOL (UNII: 506T60A25R)				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:10202-853- 14	1 in 1 BLISTER PACK	12/08/2016				
1		14 g in 1 TUBE; Type 0: Not a Combination Product					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part356	12/08/2016			

Labeler - 7-ELEVEN, INC. (007347602)

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