#### TOP QUALITY MFG. TOPICAL ANESTHETIC- benzocaine gel Top Quality Manufacturing, 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.

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## **Active Ingredient**

Benzocaine 200mg (in each g)

#### Purpose

Oral Anesthetic

#### Use

For oral mucosa use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

## 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 the blood. This can occur even if you have used this product before. Stop use and seek immediate medical 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 on patients with 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 physician. If sore mouth symptoms do not improve in 7 days; irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your physician promptly.
- for teething
- in children under 2 years of age

When using this product Avoid contact with eyes. If contact occurs, flush with water.

**Do not exceed recommended dosage.** If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast feeding, ask a physician before use.

## Keep out of reach of children.

#### Directions

- Apply only amount needed to the oral mucosa to prevent or relieve pain.
- children under 2 years of age: do not use

## **Other Information**

Store at 59° - 86°F (15°-30°C). Protect from freezing.

#### **Inactive Ingredients**

flavoring, PEG 3350, PEG 400, sodium saccharin. May contain blue #1, green #3, green #5, red #3, red #28, red #40, yellow #5, (tartrazine), yellow #6, as a color additive.

## **Questions or comments?**

(800) 483-8559



## TOP QUALITY MFG. TOPICAL ANESTHETIC

benzocaine gel

Ingredient Name         Basis of Strength         Strength           BENZOCAINE (UNII: UJRSY48]W5) (BENZOCAINE - UNII:UJRSY48]W5)         BENZOCAINE         200 mg in 1 g           Inactive Ingredients         Ingredient Name         Strength           POLYETHYLENE GLYCOL 3350 (UNII: GZM7P15E5P)         POLYETHYLENE GLYCOL 3350 (UNII: GZM7P15E5P)         POLYETHYLENE GLYCOL 3050 (UNII: GSM2915GQ)           SACCHARIN SODIUM (UNII: SB82UX40TY)         FDAC YELLOW NO. 5 (UNII: 173W82F1M)         FDAC YELLOW NO. 5 (UNII: 173W82F1M)           FDAC YELLOW NO. 5 (UNII: 173W82F1M)         FDAC RED NO. 3 (UNII: 8920N80F1S)         FDAC RED NO. 40 (UNII: WZB912X0A)           FDAC RED NO. 40 (UNII: WZB912X0A)         FDAC RED NO. 3 (UNII: 8920N80F1S)         FDAC RED NO. 3 (UNII: 8920N80F1S)           FDAC GREEN NO. 3 (UNII: 767IP0YSMH)         FDAC GREEN NO. 5 (UNII: 8960N8051S)         FDAC GREEN NO. 5 (UNII: 8960N8051S)           DAC GGREEN NO. 5 (UNII: 8J6RDU8L9X)         Imprint Code         FOR           Product Characteristics         Size         F           Contains         STRAWBERRY         Imprint Code         Marketing End Date           Product Information         Intro  Marketing Start         Marketing End Date           Marketing Information         1/101/2018         Marketing End Date	benzocaine gel							
Product Type       HUMAN OTC DRUG       Item Code (Source)       NDC:69301-001         Route of Administration       DENTAL       Basis of Strength       Strength         Active Ingredient/Active Moiety       Basis of Strength       Strength         BENZOCAINE (UNII: U3RSY48JW6) (BENZ OCAINE - UNII:U3RSY48JW5)       BENZOCAINE       200 mg in 1 g         Inactive Ingredient/Active Moiety       Ingredient Name       Basis of Strength       Strength         POLYETHYLENE GLYCOL 3350 (UNII: 62MP15ESP)       BENZOCAINE       Strength         POLYETHYLENE GLYCOL 400 (UNII: 6887843GQ)       SaccHARIN SoBIUM (UNII: 5882UX40TY)       FOAC YELLOW NO. 5 (UNII: 1753W62F1N)       FOAC YELLOW NO. 5 (UNII: 1753W62F1N)         FOAC YELLOW NO. 5 (UNII: 19300R6015)       DEGK RED NO. 3 (UNII: 19300R6015)       DEGK RED NO. 3 (UNII: 19300R6015)       Size         FOAC GREEN NO. 5 (UNII: 8]6RDU8L9X)       Imprint Code       Imprint Code         Product Characteristics       Size       Imprint Code         Contains       30 g in 1 JRR. Type 0: Not a Combination       11/01/2018       Marketing End Date         Hem Code       Package Description       Marketing Start       Marketing End Date         Date       Product Characteristion       Marketing End Date       Marketing End Date	Product Inform	nation						
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Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength BENZOCAINE (UNII: U3RS Y48)W6) (BENZOCAINE - UNII:U3RS Y48)W5) BENZOCAINE 200 mg in 1 g Inactive Ingredients Ingredient Name Strength POLYETHYLENE GLYCOL 3350 (UMII: G2M7P15ESP) POLYETHYLENE GLYCOL 3350 (UMII: G2M7P15ESP) POLYETHYLENE GLYCOL 3350 (UMII: G2M7P15ESP) POLYETHYLENE GLYCOL 3050 (UMII: B282UX40TY) FD6C YELLOW NO.5 (UMI: 1753W221M) FD6C YELLOW NO.5 (UMI: 1753W221M) FD6C YELLOW NO.5 (UMI: 1753W221M) FD6C RED NO. 3 (UMI: PNZH5LOQY) FD6C RED NO. 3 (UMII: W289127XOA) FD6C RED NO. 40 (UMII: W289127XOA) FD6C RED NO. 40 (UMII: W289127XOA) FD6C GRED NO. 3 (UMII: B367U38) FD6C GRED NO. 3 (UMII: B367U38) FD7 FD7 FD7 FD7 FD7 FD7 FD7 FD7				item C	.oae (Source)	NDC	:09301-001	
Ingredient Name         Basis of Strength         Strength           BENZOCAINE (UNII: UJRSY48]W5) (BENZOCAINE - UNII:UJRSY48]W5)         BENZOCAINE         200 mg in 1 g           Inactive Ingredients         Ingredient Name         Strength           POLYETHYLENE GLYCOL 3350 (UNII: GZM7P15E5P)         POLYETHYLENE GLYCOL 3350 (UNII: GZM7P15E5P)         POLYETHYLENE GLYCOL 3050 (UNII: GSM2915GQ)           SACCHARIN SODIUM (UNII: SB82UX40TY)         FDAC YELLOW NO. 5 (UNII: 173W82F1M)         FDAC YELLOW NO. 5 (UNII: 173W82F1M)           FDAC YELLOW NO. 5 (UNII: 173W82F1M)         FDAC RED NO. 3 (UNII: 8920N80F1S)         FDAC RED NO. 40 (UNII: WZB912X0A)           FDAC RED NO. 40 (UNII: WZB912X0A)         FDAC RED NO. 3 (UNII: 8920N80F1S)         FDAC RED NO. 3 (UNII: 8920N80F1S)           FDAC GREEN NO. 3 (UNII: 767IP0YSMH)         FDAC GREEN NO. 5 (UNII: 8960N8051S)         FDAC GREEN NO. 5 (UNII: 8960N8051S)           DAC GGREEN NO. 5 (UNII: 8J6RDU8L9X)         Imprint Code         FOR           Product Characteristics         Size         F           Contains         STRAWBERRY         Imprint Code         Marketing End Date           Product Information         Intro  Marketing Start         Marketing End Date           Marketing Information         1/101/2018         Marketing End Date	Route of Adminis	stration	DENTAL					
Ingredient Name         Basis of Strength         Strength           BENZOCAINE (UNII: UJRSY48]W5) (BENZOCAINE - UNII:UJRSY48]W5)         BENZOCAINE         200 mg in 1 g           Inactive Ingredients         Ingredient Name         Strength           POLYETHYLENE GLYCOL 3350 (UNII: GZM7P15E5P)         POLYETHYLENE GLYCOL 3350 (UNII: GZM7P15E5P)         POLYETHYLENE GLYCOL 3050 (UNII: GSM2915GQ)           SACCHARIN SODIUM (UNII: SB82UX40TY)         FDAC YELLOW NO. 5 (UNII: 173W82F1M)         FDAC YELLOW NO. 5 (UNII: 173W82F1M)           FDAC YELLOW NO. 5 (UNII: 173W82F1M)         FDAC RED NO. 3 (UNII: 8920N80F1S)         FDAC RED NO. 40 (UNII: WZB912X0A)           FDAC RED NO. 40 (UNII: WZB912X0A)         FDAC RED NO. 3 (UNII: 8920N80F1S)         FDAC RED NO. 3 (UNII: 8920N80F1S)           FDAC GREEN NO. 3 (UNII: 767IP0YSMH)         FDAC GREEN NO. 5 (UNII: 8960N8051S)         FDAC GREEN NO. 5 (UNII: 8960N8051S)           DAC GGREEN NO. 5 (UNII: 8J6RDU8L9X)         Imprint Code         FOR           Product Characteristics         Size         F           Contains         STRAWBERRY         Imprint Code         Marketing End Date           Product Information         Intro  Marketing Start         Marketing End Date           Marketing Information         1/101/2018         Marketing End Date								
BENZOCAINE (UNII: U3RSY4BJW5) (BENZOCAINE - UNII:U3RSY4BJW5) BENZOCAINE 200 mg in 1 g  Inactive Ingredients  Ingredient Name Strength POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15ESP) POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ) SACCHARIN SODIUM (UNII: SB8ZUX40TY) FD6C YELLOW NO. 5 (UMI: 753W62TM) FD6C YELLOW NO. 5 (UMI: 775W62TM) FD6C YELLOW NO. 5 (UMI: 775W62TM) FD6C RED NO. 3 (UMI: 775W62TM) FD6C RED NO. 40 (UMI: W2B9127XOA) FD6C RED NO. 40 (UMI: W2B9127XOA) FD6C RED NO. 40 (UMI: W2B9127XOA) FD6C RED NO. 5 (UMII: 767P0YSNH) D6C GREEN NO. 5 (UMII: 767P0YSNH) D6C GREEN NO. 5 (UMII: 3P30H8601S) D6C RED NO. 28 (UMII: 3P30H8601S) D6C RED NO. 5 (UMII: 3P30H8601S) D6C GREEN NO. 5 (UMII: 3P30H8601S) D7C M200H8450  FOOL CONT FOR TOT STORE STRENG S	Active Ingredient/Active Moiety							
Inactive Ingredients       Ingredient Name       Strength         POLYETHYLENE GLYCOL 3350 (UNII: 62M7P15E5P)       Strength         POLYETHYLENE GLYCOL 400 (UNII: 68978945GQ)       SACCHARIN SODIUM (UNII: 588204307Y)       SACCHARIN SODIUM (UNII: 588204307Y)         FD&C YELLOW NO. 5 (UNII: 1753W82F3M)       FD&C YELLOW NO. 6 (UNII: 1753W82F3M)       FD&C YELLOW NO. 5 (UNII: 1753W82F3M)         FD&C YELLOW NO. 5 (UNII: 1753W82F3M)       FD&C YELLOW NO. 6 (UNII: 1753W82F3M)       FD&C YELLOW NO. 6 (UNII: 1753W82F3M)         FD&C RED NO. 3 (UNII: 1783W12510)       FD&C SCORE       FD&C YELLOW NO. 5 (UNII: 3P30NR6015)         D&C GREEN NO. 3 (UNII: 3P30NR6015)       D&C GREEN NO. 5 (UNII: 3P30NR6015)       D         D&C GREEN NO. 5 (UNII: 3P30NR6015)       D&C GREEN NO. 5 (UNII: 3P30NR6015)       D         D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)       Imprint Code       Size         Product Characteristics       Size       Imprint Code         Color       red       Score       Size         Flavor       STRAWBERY       Imprint Code       Date         Packaging       # tem Code       Package Description       11/01/2018       Marketing End Date         1       30 gi n 1 JAR; Type 0: Not a Combination       11/01/2018       11/01/2018       T	Ingredient Name Basis of					trength	Strength	
Ingredient Name     Strength       POLYETHYLENE GLYCOL 3350 (UNII: G2/07P15E5P)	BENZOCAINE (UNII:	U3RSY48JW5)			BENZOCAINE	BENZOCAINE 2		
Ingredient Name     Strength       POLYETHYLENE GLYCOL 3350 (UNII: G2/07P15E5P)								
POLYETHYLENE GLYCOL 3350 (UNII: 62M7P15E5P)         Image: Content of Content	Inactive Ingredients							
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ) SACCHARIN SODIUM (UNII: SB8ZUX40TY) FD&C YELLOW NO. 5 (UNII: F733W82F1M) FD&C RED NO. 3 (UNII: PN2ZH5LOQY) FD&C RED NO. 40 (UNII: WZB9127XOA) FD&C RED NO. 40 (UNII: WZB9127XOA) FD&C GREEN NO. 3 (UNII: P3930NR601S) D&C GREEN NO. 3 (UNII: 7671P0Y5NH) D&C GREEN NO. 5 (UNII: 8)GRDUBL9X) Product Characteristics Color red Size			Strength					
SACCHARIN SODIUM (UNII: SB8Z UX40TY) FD&C YELLOW NO. 5 (UNII: H753W82F1M) FD&C YELLOW NO. 6 (UNII: H77VEI93A8) FD&C RED NO. 3 (UNII: P72X H5LOQY) FD&C RED NO. 40 (UNII: WZ 89127XOA) FD&C GRED NO. 40 (UNII: WZ 89127XOA) FD&C GREEN NO. 3 (UNII: 393ONR601S) D&C GREEN NO. 3 (UNII: 393ONR601S) D&C GREEN NO. 3 (UNII: 767P0YSNH) D&C GREEN NO. 5 (UNII: 767P0YSNH) D&C GREEN NO. 5 (UNII: 8J6RDU8L9X) Product Characteristics Color red Score Shape red Size Flavor STRAWBERRY Flavor STRAWBERRY Packaging	POLYETHYLENE GL							
Fb&C YELLOW NO. 5 (UNII: 1753WB2F1M)       Image: Constant of	POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)							
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)       Image: State	SACCHARIN SODIUM (UNII: SB8ZUX40TY)							
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)         Image: State of Sta	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)							
FD&C RED NO. 40 (UNII: WZB9127XOA)       Image: State s	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)							
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)       Image: State of the state o	FD&C RED NO. 3 (UNII: PN2ZH5LOQY)							
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)       Image: Constant of the second o	FD&C RED NO. 40 (UNII: WZ B9127XOA)							
Dé C RED NO. 28 (UNII: 767/P0Y5NH)   Dé C GREEN NO. 5 (UNII: 8J6RDU8L9X)     red   Size   Imprint Code   STRAWBERRY   Imprint Code   Contains   Packaging   # Item Code   Package Description Marketing Start Date   1 NDC:69301-001-   30 g in 1 JAR; Type 0: Not a Combination   1 NDC:69301-001-   30 g in 1 JAR; Type 0: Not a Combination   1 NDC:69301-001-   30 g in 1 JAR; Type 0: Not a Combination   1 NDC:69301-001-   30 g in 1 JAR; Type 0: Not a Combination   1 NDC:69301-001-   30 g in 1 JAR; Type 0: Not a Combination   1 NDC:69301-001-   30 g in 1 JAR; Type 0: Not a Combination   1 NDC:69301-001-   30 G in 1 JAR; Type 0: Not a Combination   1 NDC:69301-001-   30 G in 1 JAR; Type 0: Not a Combination   1 NDC:69301-001-   30 G in 1 JAR; Type 0: Not a Combination   1 NDC:69301-001-   30 Marketing Start   Marketing Marketing End   Date Date	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)							
Bec GREEN NO. 5 (UNII: 8j6RDU8L9X)       Image: Sige state st	FD&C GREEN NO. 3 (UNII: 3P3ONR601S)							
Product Characteristics         red       Score         Size         Size         Imprint Code         Part and the set of the set	D&C RED NO. 28 (UNII: 767IP0Y5NH)							
Color       red       Score       Imprint Code         Shape       STRAWBERRY       Imprint Code         Contains       STRAWBERRY       Imprint Code         Vertice       Stration Strate       Marketing Starte         Marketing Starte       30 g in 1 JAR; Type 0: Not a Combination       11/01/2018         NDC:69301-001-       30 g in 1 JAR; Type 0: Not a Combination       11/01/2018	D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)							
Color       red       Score       Imprint Code         Shape       STRAWBERRY       Imprint Code         Contains       STRAWBERRY       Imprint Code         Vertice       Stration Strate       Marketing Starte         Marketing Starte       30 g in 1 JAR; Type 0: Not a Combination       11/01/2018         NDC:69301-001-       30 g in 1 JAR; Type 0: Not a Combination       11/01/2018								
Color       red       Score       Imprint Code         Shape       STRAWBERRY       Imprint Code         Contains       STRAWBERRY       Imprint Code         Vertice       Stration Strate       Marketing Starte         Marketing Starte       30 g in 1 JAR; Type 0: Not a Combination       11/01/2018         NDC:69301-001-       30 g in 1 JAR; Type 0: Not a Combination       11/01/2018	Product Characteristics							
Shape       Size					Score			
File STRAWBERRY     STRAWBERRY     Imprint Code     Package Description     Marketing Start   Date     Marketing Start   Strategory     Application Number or Monograph     Marketing Start   Date     Marketing Start   Date     Marketing Start   Marketing Start     Marketing Start     Marketing Start     Marketing Start     Marketing Start     Marketing Start     Marketing Start     Marketing Start     Marketing Start     Marketing Start     Application Number or Monograph     Marketing Start     Marketing Start     Marketing Start     Application Number or Monograph     Marketing Start     Marketing Start								
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Marketing Start Date         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:69301-001- 30 g in 1 JAR; Type 0: Not a Combination Product       11/01/2018       11/01/2018         Marketing Line       Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date								
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#       Item Code       Package Description       Date       Date         1       NDC:69301-001- 30       30 g in 1 JAR; Type 0: Not a Combination Product       11/01/2018       11/01/2018         Marketing Information       Marketing Start       Marketing End Date         OTC menagraph pet       OTC menagraph pet       Image: Marketing Start       Marketing End Date					Marketing Start	Ma	rketina End	
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# Labeler - Top Quality Manufacturing, Inc. (113630649)

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Top Quality Manufacturing, Inc.