

**IPANA 20% BENZOCAINE TOPICAL- benzocaine gel**  
**Maxill 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 Ingredients (in each gram)**

Benzocaine 200mg

**Purpose**

Oral Anesthetic

**Use**

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

**Warnings**

**Allergy alert:** Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.

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

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

**Stop use and consult a health care practitioner** if the following symptoms appear: weakness, confusion, headache, difficulty breathing, and/or pale, grey or blue colored skin, as these may be signs of methemoglobinemia, a rare disorder, which may appear up to 2 hours after use.

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

**If pregnant or breastfeeding,** ask a health professional before use.

**Keep out of reach of children.**

**Directions**

Apply only amount needed to the oral mucosa to prevent or relieve pain.

**Other Information**

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

### **Inactive Ingredients**

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

### **Questions?**

1-855-462-9455 or 1-519-631-7370

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## Drug Facts (continued)

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Manufactured for:

**maxill inc.**

Cortland, OH, USA 44410  
www.maxill.com

99093750 REV.2016/08

**PEEL BACK**  
For Drug Facts

TO REORDER,  
CALL OR VISIT

**1-855-462-9455**  
**www.maxill.com**

**MADE IN USA**  
REV.2016/08

**ipana**

**20% BENZOCAINE**  
**TOPICAL GEL**

**Net Wt. 1 oz. (28 g)**

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69510-358
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	STRAWBERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69510-358-30	28 g in 1 JAR; Type 0: Not a Combination Product	08/01/2016	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part356	08/01/2016	

**Labeler** - Maxill Inc. (079343581)

