IPANA 20% BENZOCAINE TOPICAL- benzocaine gel
Maxill Inc.

Ipana 20% Benzocaine Topical Strawberry

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

Drug Facts

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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)

IPANA 20% BENZOCAINE TOPICAL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69510-358
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
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	08/01/2016	

Labeler - Maxill Inc. (079343581)