DENTEK INSTANT PAIN RELIEF MAXIMUM STRENGTH- benzocaine liquid
Team Technologies, 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.

DenTek Instant Pain Relief

Active ingredients

Benzocaine 20%

Purpose

Oral Pain Reliever

Use for the temporary relief of pain due to: **.** toothaches **.** canker sore **.** cold sores **.** sore gums

Warnings

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

When using this product . avoid contact with the 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 dentist or doctor if. swelling, rash or fever develops **.** irritation, pain or redness persists or worsens **.** symptoms do not improve in 7 days

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions. dip applicator into liquid

Adults and children 2 years of age and older: Apply a small amount of product to the affected area. Use up to 4 times daily or as directed by a dentist or doctor.

Children under 12 years of age: Should be supervised in the use of this product.

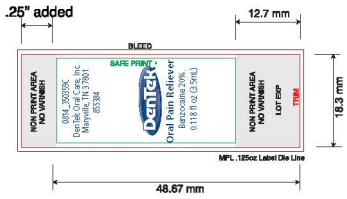
Children under 2 years of age: Ask a dentist or doctor.

Other information . do not use if safety seal on carton is broken. **.** this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted. **.** do not use continuously

Inactive ingredients: Carbowax 400, Peppermint Oil, Spearmint Oil, Sucralose

Questions or comments? Call us 800-4DENTEK (433-6835) M-F 8am - 5pm EST or email us at info@DenTek.com

DenTek Instant Pain Relief Inner Vial Label



Project Name: benzo label_adult
Artwork Initiated: 08/01/13
Artist: LK
Supplier: Amerigraph
Require Addit. Vender Routing: n

white label

654 C

DenTek Instant Pain Relief Outer Carton Label

DENTEK INSTANT PAIN RELIEF MAXIMUM STRENGTH

benzocaine liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67659-410(NDC:60630-077)
Route of Administration	DENTAL, TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	10 mg in 1 mL
PEPPERMINT OIL (UNII: AV092KU4JH)	2.2 mg in 1 mL
SPEARMINT OIL (UNII: C3M81465G5)	3.3 mg in 1 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	784.5 mg in 1 mL

Product Characteristics

Color	yellow (colorless to light yellow liquid)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67659-410-04	1 in 1 CARTON	07/31/2015	
1	NDC:67659-410-03	3.5 mL in 1 VIAL, GLASS; 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	06/20/2002	

Labeler - Team Technologies, Inc (192339703)

Registrant - Team Technologies, Inc (192339703)

Establishment

Name	Address	ID/FEI	Business Operations
Team Technologies, Inc		079527756	relabel(67659-410) , repack(67659-410)

Revised: 10/2022 Team Technologies, Inc