20/20 TOPICAL ANESTHETIC- benzocaine strip Advanced Dental Anesthetics

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.

20/20 Topical Anesthetic Strip

Drug Facts

Active ingredient

Benzocaine 20%

Purpose

Oral pain reliever

Use

Temporary relief of oral pain

Warnings

Consult a physician or qualified health care professional prior to using this product if you have any medical conditions, or if you are using any prescription drug.

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.

KEEP OUT OF REACH OF CHILDREN.

This carrying case may present a choking hazard. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

Stop use and ask doctor if

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

Directions

Not for use by individuals under 12 years of age.

Dosage: 1 strip, not more than 4 per day

- Remove 1 strip from carrying case.
- Place strip onto area of desired anesthesia
- Allow strip to dissolve completely

Other

Storage conditions: 55° to 78° Fahrenheit in a dry place. Keep foil pouch for information. KEEP AWAY FROM LIGHT

Inactive ingredients

Hydroxypropyl Methyl Cellulose, Gylcerine, Peppermint Oil Flavor, Gum Arabic, Sodium Carboxy Methyl Cellulose, Sucralose, Polysorbate 80, Sodium Copper Chlorophyllin.

Distributed by: AdvancedDENTAL ANESTHETICS

PRINCIPAL DISPLAY PANEL - 24 Strip Pouch Label

Active Ingredient: Benzocaine 20%

20/20 Topical Anesthetic Strip 24 STRIPS Active Ingredient: Benzocaine 20% **Topical Anesthetic Strip** 24 STRIPS

> **Topical Anesthetic Strip** www.2020strip.com

NDC 76484-948-24

1 Cassette 24 Strips each

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Active ingredient

Purpose

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Use Temporary relief of oral pain

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**These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure, or prevent any disease.**





20/20 TOPICAL ANESTHETIC

benzocaine strip

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76484-948

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	10 mg

Inactive Ingredients				
Ingredient Name	Strength			
HYPROMELLOSE 2208 (3 MPA.S) (UNII: 9H4L916OBU)	18.44 mg			
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)				
HYPROMELLOSE 2208 (4000 MPA.S) (UNII: 39J80LT57T)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
ACACIA (UNII: 5C5403N26O)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)				
SODIUM COPPER CHLOROPHYLLIN (UNII: 1D276TYV9O)				

Product Characteristics			
Color	GREEN (Light Green)	Score	
Shape		Size	

Flavor	Imprint Code	
Contains		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76484-948-24	1 in 1 POUCH		
1		24 in 1 CASE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part356	02/28/2012	

Labeler - Advanced Dental Anesthetics (969804223)

Establishment			
Name	Address	ID/FEI	Business Operations
Atlas Operations Inc		946369055	MANUFACTURE, PACK, LABEL

Revised: 5/2012 Advanced Dental Anesthetics