

RITE AID LIQUID ANESTHETIC ORAL PAIN RELIEF - benzocaine gel

Rite Aid Corporation

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.

drug facts

Active ingredient

Purpose

Benzocaine, 20%.....Anesthetic

Uses

- temporary relieves pain associated with: - canker sores
- minor irritation or injury of mouth and gums - minor dental procedures
- minor irritation of mouth and gums caused by dentures or orthodontic appliances

also for the temporary relief of sore gums due to teething in children 2 years of age and older

Keep out of reach of children. If more than is used for oral anesthetic is accidentally swallowed, get medical help or contact a Poison Control Center right away.

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Warnings

Fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms persist, contact your doctor.

Do not use - for more than directed - for more than 7 days, unless directed by a dentist or doctor
- if you have a history of allergy 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

Stop use and ask a doctor if:

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

Keep out of reach of children. If more than used for oral anesthetic is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions Adults and children 2 years of age and older

- apply to the affected area - allow to remain in place at least 1 minute and then spit out
- use up to four times a day or as directed by a dentist or doctor

For teething apply to affected area not more than 4 times daily, or as directed by a dentist or doctor

Children under 2 years of age consult a dentist or doctor

Children under 12 years of age should be supervised in the use of this product

Inactive Ingredients

PEG-8, propylene glycol, flavor, benzyl alcohol, methylparaben, saccharin, red 40, yellow 10, blue 1

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SAFETY SEALED. DO NOT USE IF NECK SEAL ON BOTTLE IS BROKEN OR MISSING.

BX004RAD10Z-2



ITEM 0030869



MADE IN USA
DISTRIBUTED BY:
RITE AID, 30 HUNTER LANE
CAMP HILL, PA 17011

This product is not manufactured
or distributed by Wyeth
Laboratories, Inc., owner of the
registered trademark Anbesol.

NET WT 1 FL OZ (30 mL)

benzocaine 20%

liquid anesthetic
oral pain relief

fast relief from the pain of
toothache, cold sores, canker
sores, dentures, swollen gums

benzocaine 20%

oral
pain relief

liquid anesthetic

MAXIMUM
STRENGTH





RITE AID LIQUID ANESTHETIC ORAL PAIN RELIEF

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-3950
Route of Administration	ORAL		

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
BENZYL ALCOHOL (UNII: LKG8494WBH)	

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SPEARMINT OIL (UNII: C3M81465G5)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN (UNII: FST467XS7D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-3950-6	1 in 1 CARTON		
1		30 mL in 1 TUBE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part356	07/08/2010	

Labeler - Rite Aid Corporation (014578892)

Registrant - Pharma Pac, LLC (140807475)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 7/2010

Rite Aid Corporation