

FAMILY WELLNESS REGULAR- benzocaine 10% gel
Velocity Pharma LLC

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.

Family wellness oral pain relief gel

Active ingredient

Benzocaine 10%

Purpose

Oral pain reliever

Use

- for the temporary relief of pain due to toothaches

Warnings

☐**Methemoglobinemia:** ☐see package warning.

☐**Do not use**

- more than directed
- for more than 7 days unless directed by a physician or healthcare provider
- For teething
- in children under 2 year of age.

☐**Stop use and ask a physician 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 or allergic reaction, get medical help or contact a Poison Control Center right away

☐**Directions** - cut open tip of tube on score mark

- **Adults and children 2 years of age and over** - Apply a small amount of product to the cavity and around gum surrounding the teeth. Use up to 4 times daily or as directed by a physician or healthcare provider
- **Children between 2 and 12 years of age** - Should be supervised in the use of this product
- **Children under 2 years of age** - Ask a physician or healthcare provider

Other information

- do not use if tape seal on the flaps of outer packaging are damaged or missing

- Retain outer packaging for full product uses, directions and warnings.

Inactive ingredients

ammonium glycyrrhizate, flavor, polyethylene glycol, sodium saccharin, sorbic acid

COMPARE TO ORAJEL[®] MEDICATED[®]

FAMILY wellness[™]

ORAL PAIN RELIEF

Relieves Pain Instantly

for Toothache

GEL

• Relieves Oral Pain with 10% Benzocaine

• Relieves Oral Pain with 10% Benzocaine

0.33 oz (9 g)

DISTRIBUTED BY:
MIDWOOD BRANDS, LLC,
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320, USA
MADE IN INDIA

NOT 100% SATISFIED?
Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

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ORAL PAIN RELIEF
0.33 OZ (9.1 G)

Drug Facts

Active ingredient
Benzocaine 10%

Purpose
Oral pain reliever

Warnings
Use for the temporary relief of pain due to toothaches

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops: ■ pale, gray or blue colored skin (cyanosis) ■ headache ■ rapid heart rate ■ shortness of breath ■ dizziness or lightheadedness ■ fatigue or lack of energy

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

Do not use more than directed ■ for more than 7 days unless directed by a dentist or doctor ■ for teething ■ in children under 2 years of age

Stop use and ask a doctor if ■ 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. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions
adults and children 2 years of age or older ■ apply to affected area up to 4 times daily or as directed by a dentist or doctor
children between 2 and 12 years of age ■ ask a doctor before use. Should be supervised in the use of this product
children under 2 years of age ■ do not use

Other information ■ This preparation is intended for use in cases of toothache, only as temporary expedient until a physician can be consulted ■ do not use if tape seal on flaps are damaged or missing

Inactive ingredients
ammonium glycyrrhizate, flavor, polyethylene glycol-400, polyethylene glycol-4000, sodium saccharin, sorbic acid

Questions or comments? Call 1-855-314-1850



FAMILY WELLNESS REGULAR

benzocaine 10% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76168-607
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	100 mg in 1g

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-607-33	1 in 1 PACKAGE	07/02/2020	
1		9 g in 1 TUBE; 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	07/02/2020	

Labeler - Velocity Pharma LLC (962198409)

Revised: 7/2020

Velocity Pharma LLC