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

Methemoglobinemla: 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 samll 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 physicaian or healthcare provider

Other information

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

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

Inactive ingredients

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

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 1 g

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