MY FAIR BABY ORAL GEL INSTANT PAIN RELIEF- benzocaine gel
Anicare Pharmaceuticals Pvt. Ltd.

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.

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oral gel

Active Ingredient

Benzocaine 7.5%

Purpose

Oral Pain Reliever

Uses

for the temporary relief of sore gums due to teething in children 2 years of age and older. For use in children under the age of 2, consult a physician or healthcare provider.

Warnings

Allergy alert: do not use this product if your baby has a history of allergy to local anesthetics such as procaine, butacaine or other "caine" anesthetics

Do not use

■ more than directed ■ for more than 7 days unless directed by a physician or healthcare provider

When using this product

■ fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms persist, consult your physician

Stop use and ask a physician if

sore mouth symptoms do not get better in 7 days ■ irritation, pain or redness does not go away ■ swelling, rash or fever develops

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

■ wash your hands ■ use your fingertip or cotton applicator to apply a small pea-size amount of Oral Gel and spread over gums ■ apply to affected area up to 4 times daily or as directed by a physician or healthcare provider ■ for children under 2 years of age, consult a physician or health care provider

Other information

do not use if tube seal under cap is broken, missing or if the tube tip is cut prior to opening

Inactive ingredients

cellulose gum, flavor, gelatin, mineral oil, pectin, petrolatum, polyethylene glycol, red 40, sodium saccharin

Package Label

MY FAIR BABY ORAL GEL INSTANT PAIN RELIEF

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47046-180
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	7.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GELATIN (UNII: 2G86QN327L)	
MINERAL OIL (UNII: T5L8T28FGP)	
PECTIN (UNII: 89NA02M4RX)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:47046-180-02	1 in 1 BOX	12/01/2020	
1	NDC:47046-180-01	14 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	06/15/2014	

Labeler - Anicare Pharmaceuticals Pvt. Ltd. (916837425)

Revised: 12/2020 Anicare Pharmaceuticals Pvt. Ltd.