EQUATE ORAL PAIN RELIEF- benzocaine gel
Sheffield Pharmaceuticals 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.

Drug Facts

Active Ingredient

Benzocaine 20%

Purpose

Oral Pain Reliever

Uses

- temporary relief of occasional minor irritation, pain and sore mouth

Warnings

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 told to do so by a dentist or doctor

Stop use and ask a doctor if

- swelling, rash or fever develops
- irritation, pain, or redness persists or worsens

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not use tube if it is cut prior to opening
- cut open tip of tube on score mark
- use your fingertip or cotton applicator to apply a small pea-size amount of Oral Pain Relief Gel
- apply to affected area up to four times daily or as directed by a dentist or physician
- Adults and children 2 years of age and older: Apply to affected area
- Children under 12 years of age should be supervised in the use of this product
- Children under 2 years of age: Consult a doctor

Other information

- store at a controlled room temperature 59°-86°F (15°-30°C)

Inactive ingredients

Benzyl Alcohol, Carboer, D&C Yellow No10, FD&C Blue No1, FD&C Red No40, Flavor, Glycerin,

Methylparaben, Polyethylene Glycol, Propylene Glycol, Sodium Saccharin

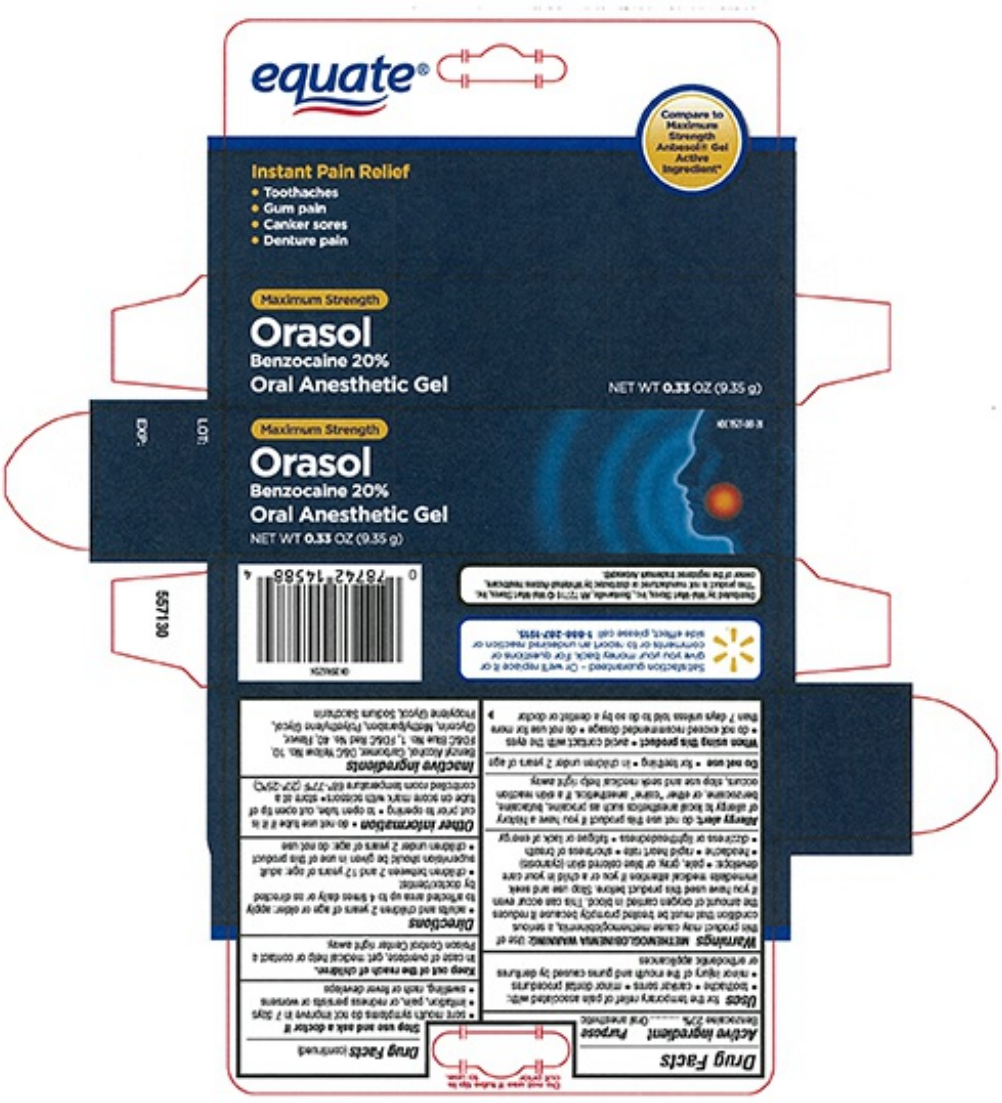
Principal Display Panel – 0.33oz Carton Label

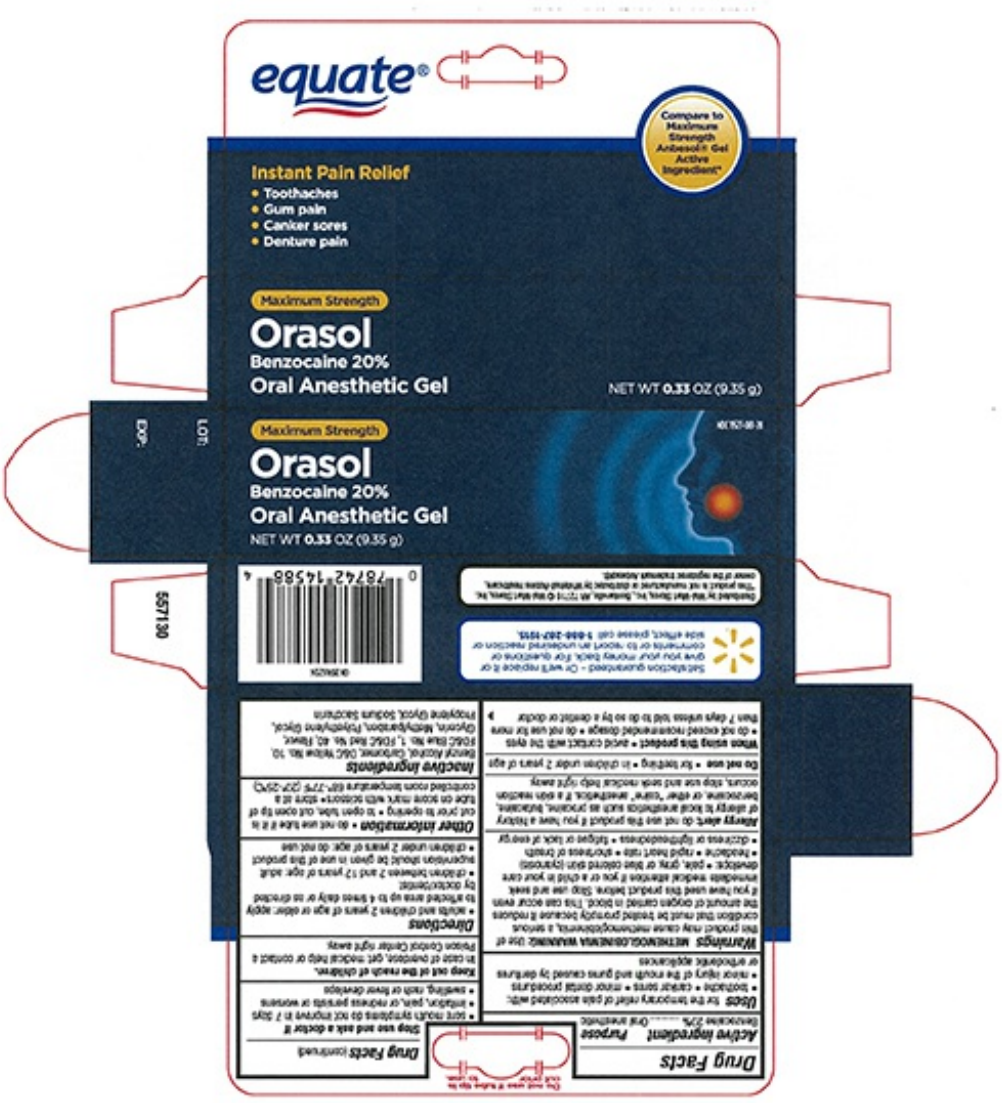
NDC 11527-081-28

Oral Pain Relief

MAXIMUM STRENGTH GEL

Benzocaine 20% NET WT. 0.33 OZ (9.35g)





Principal Display Panel – 0.33oz Tube Label

NDC 11527-081-28

Oral Pain Relief

MAXIMUM STRENGTH GEL

Benzocaine 20%

The Adult Medicine for Toothache

Fast Toothache Pain Reliever

NET WT. 0.33 OZ (9.35g)

NDC 11527-081-28

equate®

Compare to Maximum Strength Anbesol® Gel Active Ingredient*

Maximum Strength

Orasol

Benzocaine 20%

Oral Anesthetic Gel

Instant Pain Relief

NET WT **0.33** OZ (9.35 g)

Do not use if tube tip is cut prior to use.

Active ingredient Benzocaine USP 20% w/w ***Purpose*** Oral anesthetic

Uses ● for the temporary relief of pain associated with: ● toothache ● canker sores ● minor dental procedures ● minor injury of the mouth and gum caused by dentures or orthodontic appliances

Warnings Keep outer carton for complete warnings and product information. ***Keep out of reach of children.*** If swallowed, get medical help or contact a Poison Control Center right away.

Directions ● adults and children 2 years of age and older: cut open tip of tube ● apply to the affected area up to 4 times daily or as directed by a dentist or a doctor ● children under 12 years of age should be supervised in the use of this product ● children under 2 years of age, there is no recommended dosage except under the advice and supervision of a dentist or doctor ***Other information*** ● store at room temperature ***Questions?*** Call: **1-888-287-1915**

Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716 © Wal-Mart Stores, Inc.

*This product is not manufactured or distributed by Whitehall-Robins Healthcare, owner of the registered trademark Anbesol®.

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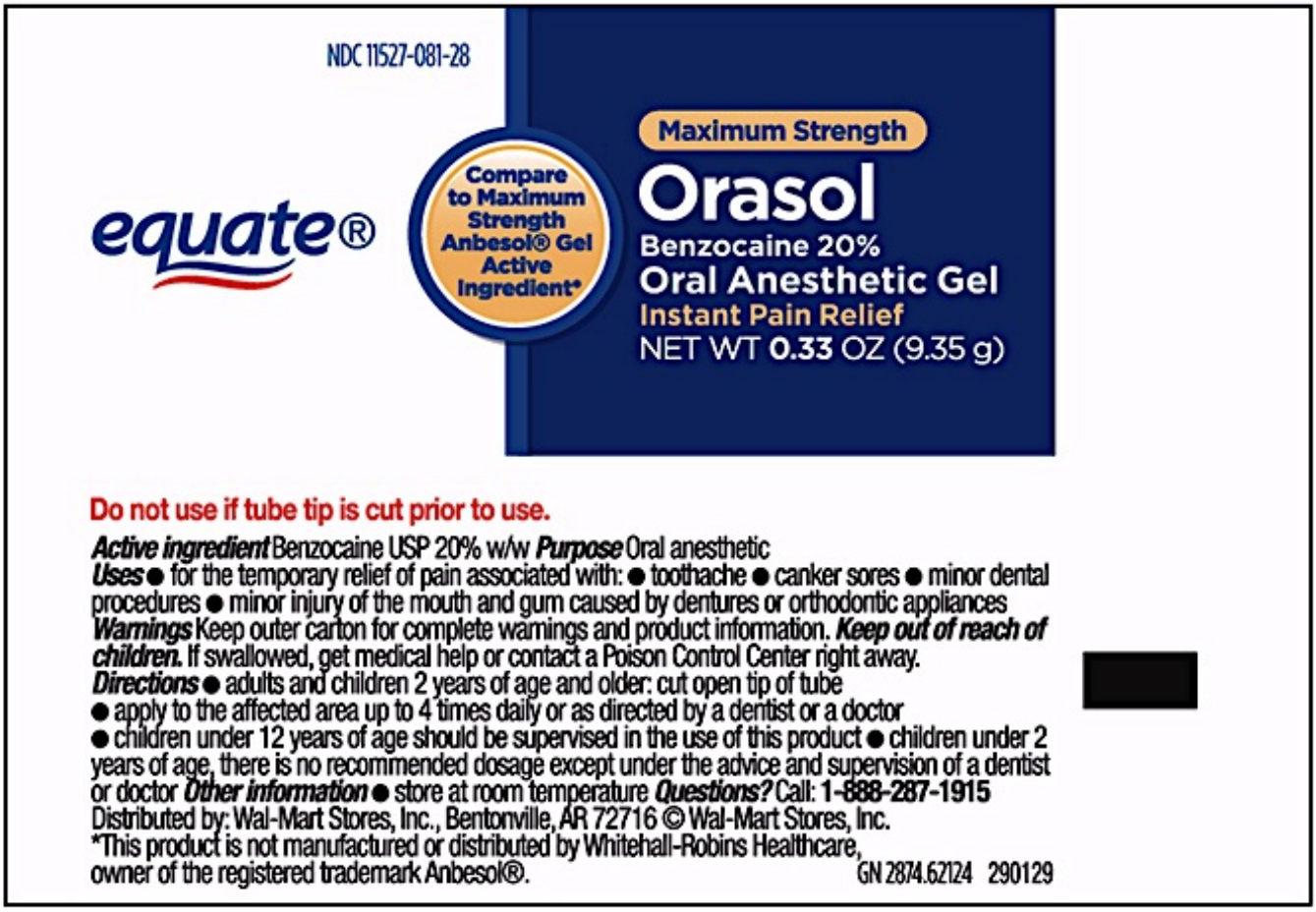

EQUATE ORAL PAIN RELIEF

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11527-081
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER 934 (UNII: Z135WT9208)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics			
Color	red	**Score**	
Shape		**Size**	
Flavor	SPEARMINT (SPEARMINT)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-081-28	1 in 1 CARTON	01/23/2007	12/31/2023
1		9.35 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	01/23/2007	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(11527-081)

Revised: 8/2020 Sheffield Pharmaceuticals LLC