## MCKESSON ORASOL GEL- benzocaine 20% gel McKesson Medical-Surgical

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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#### McKesson Orașol Gel

#### **Drug Facts**

#### Active ingredient

Benzocaine 20% (w/w)

#### **Purpose**

Oral anesthetic

#### Uses

For the temporary relief of minor pain and sore mouth associated with toothache, minor dental procedures and irritations from dentures or orthodontic appliances.

#### Warnings

#### For oral use only.

#### Do not exceed recommended dosage.

#### 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 the blood. This can occur even if you have used this product before.

Stop use and seek medical attention if you or a child in your care develops:

- pale, gray or blue colored skin (cyanosis)
- rapid heart rate
- dizziness or lightheadedness
- headache
- shortness of breath
- 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. If a skin reaction occurs, stop use and seek medical help right away.

#### Do not use

- for teething any teething related indication will not be ab appropriate use of this product
- in children under 2 years of age
- for more than 7 days unless directed by a doctor

#### Stop use and ask a dentist or doctor if

- sore mouth does not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling, rash, fever or other allergic reaction develops

#### When using this product

avoid contact with eyes

## Keep out of reach of children.

If accidentally swallowed get medical help or contact a Poison Control Center right away.

#### **Directions**

## Adults and children (2 years and older):

Dry affected area and apply medication undiluted. Use up to 4 times daily, but not more than every two hours, or as directed by a dentist or doctor.

## Children under 2 years:

Do not use

#### Other information

- do not use if packet is torn, cut or opened
- store at room temperature: 59° to 86°F (15° to 30°C)
- tamper evident sealed packets

### Inactive ingredients

PEG 400, PEG 3350, peppermint oil, sodium saccharin, sorbic acid

# Questions or comments? Call 1-800-777-4908

NDC 68599-8247-4

McKesson

Orașol Gel

**Individual Packets** 

Benzocaine 20% | Oral Anesthetic

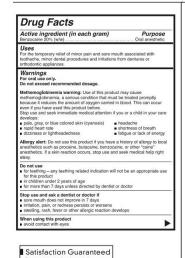
Temporary relief of minor pain and sore mouth.

**NET WT 0.75 g** 

75 Packs Per Box

Do Not Reuse

MFR # 82474



Drug Facts (continued)

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## **MCKESSON ORASOL GEL**

82474

benzocaine 20% gel

Distributed by McKesson Medical-Surgical Inc. Richmond, VA 23233 PVN A0721 Made in USA

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68599-8247
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g		

Inactive Ingredients		
Ingredient Name	Strength	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
PEPPERMINT OIL (UNII: AV092KU4JH)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SORBIC ACID (UNII: X045WJ989B)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
<b>1</b> NDC:68599-8247-4	75 in 1 BOX	10/04/2021		
1	0.75 g in 1 PACKET; Type 0: Not a Combination Product			
1				

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
part356	10/04/2021				
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date			

# Labeler - McKesson Medical-Surgical (023904428)

**Registrant -** Unifirst First Aid Corporation (832947092)

Revised: 10/2022 McKesson Medical-Surgical