

ANESTHETIC- benzocaine gel
Moore Medical 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.

Moore Medical Orasol Gel

Drug Facts

Active Ingredient (in each gram)

Benzocaine 20.0% (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 an 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 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 of age:

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 800.234.1464

Moore Medical Orasol Gel 20% Label

mooremedical

Supporting Health & Care

Reorder No. 82474
UPN# 0-0607415-82474-2

MooreBrand®
Orasol Gel 20%
75 Packets
Each Packet Net. Wt. 0.75gm

**Temporary relief of minor pain
and sore mouth.**

Distributed by:

Moore Medical LLC
Farmington, CT 06032
Manufacturer 21305178

Made in India and USA

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Stop use and ask a dentist or doctor if <ul style="list-style-type: none">■ sore mouth does not improve in 7 days■ irritation, pain, or redness persists or worsens■ swelling, rash, fever or other allergic reaction develops	
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Drug Facts (continued)	
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Directions	
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Oral Anesthetic

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To Reorder:
Call: 800.234.1464
Fax: 800.944.6667
Online: www.mooremedical.com

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ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55670-810
Route of Administration	TOPICAL		

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 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55670-810-01	75 in 1 BOX	07/12/2012	05/31/2024
1		0.75 g in 1 PACKET; 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	07/12/2012	05/31/2024

Labeler - Moore Medical LLC (051420107)**Registrant** - Unifirts First Aid Corporation (832947092)

Revised: 10/2022

Moore Medical LLC