

GOODSENSE ORAL PAIN RELIEF- benzocaine gel
Geiss, Destin and Dunn, Inc.

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.

GoodSense Oral Pain Relief Gel 0.5oz (191)

Active ingredient	Purpose
Benzocaine 20%.....	Oral pain reliever

Uses

- for the temporary relief of pain due to:
- toothache
- canker sores
- gum pain
- denture pain
- cheek bites

Warnings

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 blood. This can occur even if you have use this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy Alert: do not use this product if your child has 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 directed by a doctor
- for teething
- in children under 2 years of age

Stop use and ask a doctor if

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Adults and children 2 years of age and older	Remove cap and cut tip of tube. Apply a small amount of product to the cavity and around gum surrounding the teeth. Use up to 4 times daily or as directed by a dentist or doctor.
Children under 12 years of age.	Should be supervised in the use of this product.
Children under 2 years of age.	Do not use.

Other information

- store at 20-25°C (68°-77°F)
- this preparation is intended for use in cases of toothaches, only as a temporary expedient until a dentist or doctor can be consulted
- do not use continuously

Inactive ingredients: glycerin, peppermint oil, polyethylene glycol 400, polyethylene glycol 4000, saccharin sodium, sorbitol

Questions or comments?

Call 1-888-645-8204 Monday - Friday 9AM-5PM (PST)

Distributed by:

Perrigo Direct, Inc.

Peachtree City, GA 30269

www.PerrigoDirect.com

1-888-645-8204

Made in China

GOODSENSE®

NDC 50804-191-10

Maximum Strength

SAFETY-SEALED TUBE TIP

Oral Pain Relief Gel

Benzocaine 20% (Oral Pain Reliever)

Instant Relief of Toothache Pain

Instant Relief of Toothache Pain

Benzocaine 20% (Oral Pain Reliever)

GOODSENSE®

SAFETY-SEALED TUBE TIP

Maximum Strength

Gluten Free

Oral Pain Relief Gel

Benzocaine 20% (Oral Pain Reliever)

NET WT 0.5 OZ (14g)

GOODSENSE®
Maximum Strength
Oral Pain Relief Gel
Benzocaine 20%
(Oral Pain Reliever)

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GoodSense® is a registered trademark of L. Perrigo Company.



191-20P-BX-R2
0C-MD-ZD1P105-R4

LOT & EXP.

Drug Facts (continued)

Drug Facts
Benzocaine 20%
Oral pain reliever

Purpose
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose or allergic reaction, seek medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions
Adults and children 2 years of age and older:
Remove cap and cut tip of tube. Apply a small amount of product to the cavity and around gum surrounding the teeth. Use up to 4 times daily or as directed by a dentist or doctor.

Children under 12 years of age:
Should be supervised in the use of this product.

Children under 2 years of age:
Do not use.

Other information
■ store at room temperature 20-25°C (68-77°F)
■ this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist or doctor can be consulted. Do not use continuously.

Inactive ingredients glycerin, peppermint oil, polyethylene glycol 400, polyethylene glycol 4000, saccharin sodium, sorbitol

Questions or comments?
Call 1-888-645-8204 Monday-Friday 9AM-5PM (PST)

Warnings
■ methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:
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Stop use and ask a doctor if
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■ swelling, rash or fever develops

TAMPER EVIDENT DO NOT USE IF OUTER CARTON IS OPEN OR IF TUBE TIP IS CUT PRIOR TO OPENING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

GOODSENSE ORAL PAIN RELIEF

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-191
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
MINT (UNII: FV98Z8G1TP)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50804-191-10	1 in 1 CARTON	12/18/2018	
1		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 final	part333B	05/09/2014	

Labeler - Geiss, Destin and Dunn, Inc. (076059836)

Revised: 5/2022

Geiss, Destin and Dunn, Inc.