RED CROSS ORAL PAIN RELIEF- benzocaine liquid
The Mentholatum Company

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

temporarily relieves pain associated with ■ toothache ■ canker sores ■ minor mouth irritation or injury of the mouth and gums caused by dentures or braces

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 used 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 you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other “caine” anesthetics

Do Not Use

- for teething
- in children under 2 years of age

When using this product

- do not use for more than 7 days unless directed by a dentist or doctor
- do not exceed recommended dosage

Stop use and ask a doctor if

- sore mouth symptoms do not improve in 7 days
- swelling, rash, or fever develops
- irritation, pain, or redness persists or worsens

Keep Out of Reach of Children

If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- using tweezers, immerse cotton pellet in medication
- apply pellet to affected area, then remove
- adults and children 2 years and over: use up to 4 times daily or as directed by a dentist or doctor
- children under 12 years: supervise while using this product
- children under 2 years: do not use

Inactive Ingredients

ammonium glycyrrhizate, flavor, polyethylene glycol, propylene glycol, saccharin calcium

Package/Label Principal Display Panel

Principal Display Panel

USE ONLY IF BLISTER PACKAGE IS INTACT
USE ÚNICAMENTE ESTE PRODUCTO SI EL EMPAQUE ESTA INTACTO

Drug Facts

Active ingredient — **Purpose**
Benzocaine 20% — Oral pain reliever

Uses temporarily relieves pain associated with ■ toothache ■ canker sores ■ minor mouth irritation or injury of the mouth and gums caused by dentures or braces

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 used 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 you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use: ■ for teething ■ in children under 2 years of age

When using this product ■ do not use for more than 7 days unless directed by a dentist or doctor ■ do not exceed recommended dosage

Stop use and ask a dentist or doctor if ■ sore mouth symptoms do not improve in 7 days ■ swelling, rash, or fever develops ■ irritation, pain, or redness persists or worsens

Keep out of reach of children. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ using tweezers, immerse cotton pellet in medication ■ apply cotton pellet to affected area, then remove ■ may also be applied using a clean finger

adults and children 2 years and over	use up to 4 times daily or as directed by a dentist or doctor
children under 12 years	supervise while using this product
children under 2 years	do not use

Inactive ingredients ammonium glycyrrhizate, flavor, polyethylene glycol, propylene glycol, saccharin calcium

Questions? 1-877-636-2677 MON-FRI 9 AM to 5 PM (EST)

Mentholatum ©2018 EB401005

The trademarks Red Cross & the Red Cross design are registered trademarks of The Mentholatum Co. Products bearing this trademark have no connection with the American Red Cross.

Información Farmacológica

Ingrediente activo: Benzocaina 20% ***Propósito:*** Alivio del dolor bucal. ***Usos:*** Alivio temporal del dolor relacionado con dolor de dientes, dolor por aftas, irritación menor en la boca o lesión en boca y encías causada por dentaduras o frenos

Advertencias: **Advertencia de metahemoglobinemia:** El uso de este producto puede causar metahemoglobinemia, una afección grave que debe tratarse inmediatamente debido a que reduce la cantidad de oxígeno transportado en la sangre. Esto puede ocurrir incluso si ha usado este producto anteriormente. Pare el uso y busque atención médica inmediata si usted o un niño bajo su cuidado desarrolla síntomas de: ■ piel pálida, gris o azul (cianosis) ■ dolor de cabeza ■ latidos cardíacos rápidos, (taquicardia) ■ dificultad para respirar ■ mareos o aturdimientos ■ fatiga o falta de energía **Alerta de alergia** no use este medicamento si usted es alérgico al eugenol (aceite de clavo). ***No Usar:*** ■ durante la dentición ■ en niños menores de 2 años. **Al usar este producto:** no usar durante más de 7 días a menos que lo indique un dentista o un médico. No exceder la dosis recomendada. **Suspender el uso y consultar un dentista o médico si:** los síntomas de dolor bucal no mejoran en 7 días. se desarrolla inflamación, erupción o fiebre. Persiste o empeora la irritación, dolor o enrojecimiento. **Mantener fuera del alcance lo niños.** En caso de ingerir accidentalmente una cantidad mayor de la usada para el dolor, consultar un médico o ponerse en contacto de inmediato con un Centro de Control de Envenenamiento. ***Instrucciones:*** Usar pinzas, sumergir un trozo de algodón en el medicamento. aplicar el trozo de algodón en el área afectada, y retirar. También se puede aplicar usando un dedo limpio. **Adultos y niños 2 años y mayores:** usar hasta 4 veces al día o según indique un dentista o médico. **Niños menores de 12 años:** supervisar al usar este producto. **Niños menores de 2 años:** no usar. ***Ingredientes inactivos:*** glicirrinato de amonio, sabor, polietilenglicol, propilenglicol, calcio de sacarina.

¿Preguntas? 1-877-636-2677
LUNES A VIERNES 9AM a 5PM (ESTE)

3 10742 09509 8

The Mentholatum Company, Orchard Park, NY 14127 USA

RED CROSS ORAL PAIN RELIEF

benzocaine liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-8902
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 mL

Inactive Ingredients	
Ingredient Name	**Strength**
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN CALCIUM (UNII: 5101OP7P2I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8902-1	1 in 1 BLISTER PACK	06/01/2013	
1		3.7 mL in 1 BOTTLE; 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	06/01/2013	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-8902)

Revised: 2/2023 The Mentholatum Company