

## **KROGER MAXIMUM STRENGTH- benzocaine cream**

**Kroger**

**Reference Label Set Id: 9c40aed8-3d77-422b-b34a-b3d8cd18c54d**

**Reference Label Set Id: dbb3b85c-063a-4dc6-9adc-16e48f5bd268**

*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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### **Drug Facts**

#### **Active ingredient**

Benzocaine 20.0% .....Oral pain reliever

Menthol 0.25% .....Oral pain reliever

Benzalkonium Chloride 0.1% .....Antiseptic

#### **Uses**

for the temporary relief of pain due to toothaches

to help protect against infection of minor oral irritation

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

#### **When using this product**

- 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
- symptoms do not improve in 7 days
- allergic reaction occurs

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

#### **Directions**

- cut open tip of tube on score mark
- adults and children 2 years of age and older; apply a small amount of product to the cavity and around the 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:** ask a dentist or doctor.

#### **Other Information**

- do not use if tip is cut prior to opening
- this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted

- do not use continuously
- this formula will stay in place for an extended duration of relief
- avoid using toothpaste or drinking softdrinks or fruit juices for at least one hour after applying

**Inactive ingredients**

Cellulose Gum, Gelatin, Methyl Salicylate, Mineral Oil, Pectin, Petrolatum, Polyethylene Glycol, Sodium Saccharin

Adults and children 2 years of age and older:

apply to affected area using applicator tip

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: ask a dentist or doctor.

Compare to the active ingredients in Orajel™ Severe  
Toothache & Gum Relief Plus Triple Medicated Cream.  
\*See Bottom Panel.

# SEVERE Toothache & Gum Relief

## TRIPLE MEDICATED CREAM

- Maximum strength 20% Benzocaine to relieve oral pain
- Antiseptic to help prevent infection
- Soothing menthol

# Toothache & Gum Relief

- Immediate relief of severe pain
- Long-lasting

NDC 30542-320-09



## Toothache & Gum Relief TRIPLE MEDICATED CREAM



Oral pain reliever • Antiseptic

NET WT 0.33 OZ (9.3 g)

**Tamper-Evident: Do not use if tip is cut prior to use.**

\*Orajel™ is a registered trademark of Church & Dwight Co., Inc., Ewing, NY, 08628.  
Church & Dwight Inc. is not affiliated with the Kroger Co. or this product.

DISTRIBUTED BY THE KROGER CO.  
CINCINNATI, OHIO 45202

QUALITY GUARANTEE  
800-632-6900 • www.kroger.com

80% SIZE  
12-digit UPC-A  
(non-suppressed)  
For Position Only

0 41260 37934 5

2821354R1  
5820354

<b>Drug Facts</b>
<b>Active ingredients</b> ..... Benzocaine 20%..... Menthol 0.25%..... Benzalkonium Chloride 0.1%..... Antiseptic..... Oral pain reliever..... <b>Purpose</b> .....
<b>Use</b> • for the temporary relief of pain due to toothaches • to help protect against infection of minor oral irritation
<b>Warnings</b> <b>Allergy alert:</b> do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics <b>Do not use</b> • more than directed • for more than 7 days unless told to do so by a dentist or doctor <b>Stop use and ask a doctor if</b> • swelling, rash or fever develops • irritation, pain or redness persists or worsens • symptoms do not improve in 7 days • allergic reaction occurs
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.
<b>Directions</b> • cut open tip of tube on score mark • adults and children 2 years of age and older: apply a small amount of product to the cavity and around the 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: ask a dentist or doctor
<b>Other information</b> • do not use if tip is cut prior to opening • this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted • do not use continuously • this formula will stay in place for extended duration of relief • avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying
<b>Inactive ingredients</b> Cellulose Gum, Gelatin, Methyl Salicylate, Mineral Oil, Pectin, Petroleum, Polyethylene Glycol, Sodium Saccharin

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# SEVERE Toothache & Gum Relief

TRIPLE MEDICATED CREAM

Oral pain reliever • Antiseptic NET WT 0.33 OZ (9.3 g)

**Active ingredients**

Benzocaine 20% ..... Purpose Oral pain reliever  
Menthol 0.25% ..... Oral pain reliever  
Benzalkonium Chloride 0.1% ..... Antiseptic

**Use** • for the temporary relief of pain due to toothaches • to help protect against infection in minor oral irritation **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 • symptoms do not improve in 7 days • allergic reaction occurs **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away **Directions:** • cut open tip of tube on score mark • adults and children 2 years of age and older: apply a small amount of product to the cavity and around the 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: ask a dentist or doctor **Other information:** • do not use if tip is cut prior to opening • this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted • do not use continuously • this formula will stay in place for extended duration of relief • avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying 1821354R1



## KROGER MAXIMUM STRENGTH

benzocaine cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-354
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20.00 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.25 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	0.1 g in 100 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
PECTIN (UNII: 89NA02M4RX)	
Carboxymethylcellulose Sodium (UNII: K679OBS311)	

**Product Characteristics**

<b>Color</b>	white (off white to beige tan)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	WINTERGREEN (Characteristic wintergreen)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-354-09	1 in 1 CARTON	07/29/2016	
1	NDC:30 142-354-02	9.3 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/29/2016	

**Labeler** - Kroger (006999528)**Registrant** - Lornamead (126440440)**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(30 142-354) , pack(30 142-354)

Revised: 7/2016

Kroger