

ATOPALM ORAL PAIN RELIEF - benzocaine gel
NeoPharm, USA

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.

ATOPALM Oral Pain Relief Gel

Active Ingredient

Benzocaine 10%

Purpose

Oral Pain Reliever

Use

for the temporary relief of pain due to toothaches.

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 a doctor.

Stop use and ask a doctor if

- swelling, rash or fever develops
- irritation, pain, or redness persists or worsens.

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 at score mark

Adults and children 2 years of age and older

- 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 a 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 a doctor.

Other information

- do not use if tube 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.

Inactive Ingredients

PEG-400, PEG-6000, Glycerin, Sodium Saccharin, Sorbic Acid, Flavor

Questions or information?

Call toll free 1-855 ATOPALM – (1-855-286-7256)

Labeling Information

ATOPALM Oral Pain Relief Gel

Fast Temporary Relief of Pain Due to Toothache

Benzocaine 10%

Distributed by: NeoPharm USA, 1 Oyster Bay Drive, Rumson, NJ 07760
 Made in Korea

Fast Temporary Relief of Pain Due to Toothaches

ATOPALM™

ORAL PAIN RELIEF GEL

Net Wt. 0.25 oz / 7.0 g
Benzocaine 10%

Active Ingredient Benzocaine 10%

Use for the temporary relief of pain due to toothaches

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Directions: ■ cut open tip of tube at score mark ■ adults and children 2 years of age or older, 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 a 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 a doctor.

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ATOPALM™

ORAL PAIN RELIEF GEL

Fast Temporary Relief
of Pain Due to Toothache

Drug Facts

Active Ingredient..... Purpose
Benzocaine 10%..... Oral pain reliever

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Drug Facts (continued)

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Benzocaine 10%

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Net Wt. 0.25 oz / 7.0 g

Fast Temporary Relief of Pain Due to Toothaches

ATOPALM™
ORAL PAIN RELIEF GEL

**IMMEDIATE TOOTHACHE
PAIN RELIEF**

Benzocaine 10%



ATOPALM ORAL PAIN RELIEF

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51141-0236
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-0236-7	1 in 1 BOX		
1		7 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/06/2012	

Labeler - NeoPharm, USA (965502912)

Revised: 2/2012

NeoPharm, USA