

CARMEX COLD SORE TREATMENT EXTERNAL ANALGESIC- benzocaine cream
Carma Laboratories, 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.

CARMEX COLD SORE treatment External Analgesic

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Active Ingredient

Benzocaine 10%

Purpose

External Analgesic / Anti-Itch

Uses

- For the temporary relief of symptoms of cold sores and fever blisters

Warnings

- **For external use only**
- **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** keep out of eyes. Rinse with water to remove.
- Do not exceed recommended dosage.
- **Stop use and ask a doctor or dentist if**
 - cold sore symptoms do not improve in 7 days
 - irritation, pain, or redness persists or worsens
 - swelling, rash, or fever develops

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 years of age and older: apply to affected area (lips) not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

Inactive Ingredients

cyclomethicone, polyethylene glycol 600, dimethicone, silica, petrolatum, phenyl trimethicone, PEG/PPG-19/19 dimethicone, mica, peg 12 dimethicone, titanium dioxide, polyurethane-40, menthol, tin oxide

CARMEX[®]

COLD SORE TREATMENT

External Analgesic

NET WT .07 OZ (2g)

Z06-1065 A0514

Active Ingredient Benzocaine 10%

Warnings For external use only. Keep out of eyes. Allergy alert. Keep out of reach of children. Retain packaging for full product uses, directions and warnings.

Carma Laboratories, Inc., Franklin, WI 53132 carmexcoldsore.com



CARMEX COLD SORE TREATMENT EXTERNAL ANALGESIC			
benzocaine cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 210-00 12
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZO CAINE (UNII: U3RS Y48JW5) (BENZO CAINE - UNII:U3RS Y48JW5)		BENZO CAINE	10 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
CYCLOMETHICONE (UNII: NMQ347994Z)			
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
PETROLATUM (UNII: 4T6H12BN9U)			

PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PEG/PPG-19/19 DIMETHICONE (UNII: EHH90CO7TL)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MENTHOL (UNII: L7T10EIP3A)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10210-0012-0	2 g in 1 TUBE; Type 0: Not a Combination Product	05/28/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/28/2014	

Labeler - Carma Laboratories, Inc. (006090153)

Establishment

Name	Address	ID/FEI	Business Operations
Carma Laboratories, Inc.		006090153	manufacture(10210-0012)

Revised: 10/2019

Carma Laboratories, Inc.