

3X MEDICATED TOOTHACHE AND GUM GEL- benzocaine gel

Lornamead

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.

8015603 3x Med Gel

Benzocaine 20% . . . Oral pain reliever

Menthol 0.26% . . . Oral pain reliever

Zinc chloride 0.15% . . . Oral astringent

Use

for the temporary relief of pain due to minor irritation or injury of the mouth and gums

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 * more than directed * for more than 7 days unless told to do so by a dentist or doctor * for teething * in children under 2 years of age

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: do not use

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

ammonium glycyrrhizate, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid





PLEASE LEAVE OUR CVS SLUG ON ALL FINAL ART, PRE-PRESS FILES AND CONTRACT PROOFS FOR FINAL APPROVAL

CVS pharmacy ■ ■ ■ ■ ■ ■ ■

FILE NAME	ITEM NUMBER	PRINT PROCESS
122344_CVSHee#H_Orjel_3XMed_ToothacheGel_CARTON.ai	122344	OFFSET LITHO
PROJECT #	VENDOR	PRINTER
190608125	LORNAMEAD	MODPAC
UPC or SCC#	DIELINE #	SUBSTRATE
050428433621	N/A	SBS CARTON
DATE	DESIGNER	DATE
11/04/19	MSN	

DESK NON-PRINTING COLORS

MARKS: 01
File created at 100%

Illustrator CC
RELEASE DATE: 11/15/19 - MSN

VENDOR RESPONSIBILITIES

THIS PROOF SHOULD BE USED AS A VISUAL REFERENCE FOR PROOF COLOR ONLY. This packaging is required to follow the print specifications outlined by the CVS Print Quality Management (PQM) program. Final proofing is required to be sent to 505 PQM Call for evaluation immediately following packaging mass production. All specification and evaluation information is located on the program website CVS.COM/CPM. Please contact 505 PQM Call by email: CPM@CVS.COM with any questions.

PREPRESS REQUIREMENTS

ATTENTION PRINTERS: NO colors listed in the Match Colors section of this document can be printed as a solid spot color or simulated using process color dots. These colors are not required to match to the published spot color 1.5% values within the Color Match section as outlined on the PQM program website CVS.COM/CPM. Additional: A Red Color Simulation Patch for every color must be added to the press sheet to allow for color measurement. Refer to the published Color Target Guidelines on the PQM program website CVS.COM/CPM. Vendor is responsible for proper separations per their printing press proof, including trapping, bleed and minimum tolerance values. **REPLACE UPC WITH PROPER BARS FOR YOUR SPEC. ENSURE UPC BARS** Supply. PDF for contract proof review and with its approval supply 2 subsequent contract proofs per project schedule.

LORNAMEAD, INC.

PROJECT INFO | PRODUCTION NOTES

DATE: NOVEMBER 27, 2019
PROJECT: CVS 3X MEDICATED TOOTHACHE GEL CARTON
ITEM #: 2821603R1
DIELINE #: S176273
SIZE: 1.031" X 1.031" X 3.500"
FILE NAME: CVS_3XMEDICATED_TOOTHACHEGEL_CARTON_2821603R1-0L-AI
PRINTER: MODPAC
NOTES:

APPROVALS

CREATIVE _____
MARKETING _____
R&D _____
QUALITY _____
PURCHASING _____
CEO _____

NEW YORK OFFICE | 1389 BROADWAY | 17TH FLOOR | NEW YORK, NY 10019
TORONTO OFFICE | 175 COOPER AVENUE | TORONTO, ONTARIO M5P 1K3

3X MEDICATED TOOTHACHE AND GUM GEL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62721-5603
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.26 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

Product Characteristics

Color	white (Cloudy white to beige)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62721-5603-9	7.1 g in 1 TUBE; Type 0: Not a Combination Product	06/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/05/2020	

Labeler - Lornamead (126440440)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(62721-5603)

Revised: 6/2020

Lornamead