

EUGENOL TOOTHACHE MEDICATION- eugenol liquid
Team Technologies, 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.

CVS TOOTHACHE RELIEF & REPAIR KIT (Prestige)

Active Ingredient Eugenol 85%

Purpose Toothache Relief Agent

Uses For the temporary relief of throbbing, persistent toothache due to a cavity. Visit Dentist within 48 hours of use.

Warnings

For external use only. Allergy alert: do not use if you are allergic to eugenol (clove oil).

When using this product:

- . use only in teeth with persistent throbbing pain . DO NOT SWALLOW to avoid irritation
- . avoid contact with eyes

Do not use. For more than 7 days . more than the recommended dose

Stop use and ask a dentist or doctor if. irritation persists . inflammation develops . fever and infection develop

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

Directions

Adults and children 2 to 12 years of age and older: Rinse tooth with water to remove any food particles from the cavity. Moisten a cotton pellet with 1 or 2 drops of medication and using the tweezers, place in the cavity for approximately 1 minute. Avoid touching tissues other than the tooth cavity . Apply the dose not more than four times daily or as directed by a dentist or physician.

Children 2 to 12 years of age: should be supervised in the use of this product.

Children under 2 years of age: use only under the advice of a dentist or physician.

Other information. Do not purchase if package has been opened. . Store at 46 - 90 ° F. . Cap tightly to avoid evaporation. . toothaches and open cavities indicate serious problems which need prompt attention by a dentist.

Inactive ingredient sesame oil

4.12 in



Toothache Medication: 0615-250686B

Drug Facts

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Tooth Saver: If tooth is dislodged, collect the tooth and do not try to clean it. Fill Tooth Saver container with milk or your own saliva. Place broken or whole tooth in container making certain that milk or saliva is completely covering tooth. Contact your dentist immediately. Chances of successful replantation are best if you see the dentist within 1 hour of incident.

Temporary Repair: This is a temporary remedy meant to replace a lost filling, cap, crown or inlay until you have a chance to visit your dentist and should only be removed by a dental professional. Visit dentist within 48 hours of use. Caution: To avoid infection and/or serious injury, this product should not be used if there is throbbing pain, ulceration or swelling in the affected area. If any of these symptoms exist, consult your dentist immediately. This product should not be placed on open wounds. Do not swallow. Do not use if allergic to eugenol. READ ALL OF THE DIRECTIONS CAREFULLY BEFORE USE! Wash and dry your hands. **KEEP OUT OF REACH OF CHILDREN.** Store at 66-77°F. Cap tightly to avoid evaporation.

Directions to Replace a Lost Filling: Wash the cavity area with warm water. Scoop a small amount of Temporary Filling Material from the vial, and roll into a ball between fingers. Slightly overfill the cavity and tamp into place with a cotton swab moistened in water. Close your teeth together, and gently chew or grind on the replaced filling to create a comfortable bite. Use a moist cotton swab to remove excess material from around the area. Temporary Filling Material will set softly in your mouth within a few minutes, but avoid chewing on the repair for 2-3 hours to allow the material to fully set.

Directions to Secure Loose Crowns, Caps, or Inlays: Try the crown, cap, or inlay first to see if you can fit it accurately back onto the tooth surface. If you are not able to do so, then do not proceed further. If the crown has a post attached to it or if there is tooth surface remaining inside the crown, the material may not adhere. Carefully rinse the tooth area and the inside of the crown, cap, or inlay with warm water, and do not dry. Scoop a small amount from the vial, roll into a ball between fingers, and place evenly inside the crown, cap, or inlay. Place the crown, cap, or inlay on the tooth and bite down, applying pressure to push into position. Temporary Filling Material will begin to harden within a few minutes, but avoid chewing on the repair for at least 2-3 hours to allow the material to set. Use a toothbrush to gently clear any excess material from around the crown, cap, or inlay.

Temporary Repair Ingredients: Zinc Oxide Powder, Calcium Sulfate, Petroleum Jelly, Potassium Alum, Paraffin, Aluminum Sulphate, Aluminum Phosphate, Menthol Crystals, Eugenol, Yellow Iron Oxide

Other Information: Do not purchase if package has been opened.

Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 © 2015 CVS/pharmacy CVS.com® 1-800-SHOP CVS

Temporary Repair made in Italy; Toothache Medication made in the U.S.A. Tweezer, Cotton Pellets, Applicator, and Tooth Saver made in Vietnam. V-19622



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Store Brands Packaging Group
68 Cumberland Street, Ste: 200
Woonsocket, RI 02895

Please direct questions & proofs to:
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Phone: (201) 962-7006

DATE: 07/21/2015
VENDOR: DENTEK
BRAND: CVS_HCR
FILE NAME: 975211_TOOTHACHELIEFERREPAIRKIT_CARD
ITEM NUMBER: 975211
UPCA 050428259573
PA ARTIST: CK

VENDOR PRE-PRESS RESPONSIBILITIES

- CONFIRMATION OF COLOR SPECS AS NEEDED FOR PROPER SEPARATIONS.
- TRAPPING, BLEED AND MINIMUM TOLERANCE ADJUSTMENTS TO MEET TARGET PRESS REQUIREMENTS.
- REPLACE UPO WITH PROPER BWR PER PRINTER SPECS, ENSURE UPC SCANS

LINKED IMAGE ASSETS

PRODUCTION SPECIFICATIONS

TARGET COLORS

NOTES AND AREAS OF FOCUS

ADDITIONAL SPOT COLORS ARE BRAND CRITICAL COLORS AND MUST NOT BE CONVERTED AND PRODUCED WITH PROCESS EQUIVALENT PROXY COLORS. COLOR SEPARATION SPECIFICATION SHOULD MATCH CVS PRINT QUOTATION FOR THIS JOB.

VENDOR PROOFING REQUIREMENTS

PDF CONTENT PROOF AND SUBSEQUENT CONTRACT PROOF PER PROJECT SCHEDULE.

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EUGENOL TOOTHACHE MEDICATION

eugenol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67659-415(NDC:60630-686)
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUGENOL (UNII: 3T8H1794QW) (EUGENOL - UNII:3T8H1794QW)	EUGENOL	850 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SESAME OIL (UNII: QX10HYY4QV)	150 mg in 1 mL

Product Characteristics

Color	yellow (colorless to pale yellow liquid, with odor of cloves)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67659-415-21	1 in 1 KIT	07/01/2015	
1	NDC:67659-415-23	3.7 mL in 1 VIAL, GLASS; 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	07/01/2015	

Labeler - Team Technologies, Inc (192339703)

Registrant - Team Technologies, Inc (192339703)

Establishment

Name	Address	ID/FEI	Business Operations
Team Technologies, Inc		079527756	pack(67659-415) , repack(67659-415)

Revised: 12/2021

Team Technologies, Inc