

DENTEK EUGENOL- eugenol liquid
IIMED MEDICAL MEXICANA S. DE R.L. DE C.V.

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.

DenTek Dental First Aid Kit

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

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
- avoid touching tissues other than tooth cavity
- DO NOT SWALLOW to avoid irritation
- avoid contact with eyes.

Do not use

- for more than 7 days
- more than the recommended dosage.

Stop use and ask a dentist or doctor if

- irritation persists
- inflammation develops
- if fever and infection develop.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Directions Adults and children 12 year of age and older: Rinse the tooth with water to remove any food particles from the cavity. Moisten a cotton swab with Eugenol and place in the cavity for approximately 1 minute. Avoid touching tissue other than the tooth cavity. Apply the dose not more than four times daily or as directed by dentist or physician.

Adults and children 12 years and older use up to 4 times daily or as directed by a dentist or doctor.

Children under 12 years ask a dentist or doctor.

Inactive ingredient

sesame oil

Other information

- Do not purchase if package has been opened
- Store at 68-77 o F
- Cap tightly to avoid evaporation.

DenTek Dental First Aid Kit

PRESTIGE BRANDS INC
660 White Plains Rd. Tarrytown, New York 10591
914-524-6834 artdept@prestigebrands.com

DENTEK
PRODUCT NAME: DENTAL FIRST AID KIT
COMPONENT: BLISTER CARD
SIZE:
COUNTRY: UK
JOB #: DKGB028801
TECH DRAWING #: LEGACY
UPC#: 0-47701-50032-3
NOTE: PRINTS 6/1
CARDBAK

INK COLORS

PRO CYAN	PRO MAGENTA	PRO YELLOW	PRO BLACK	PMS 654	PMS 346C	PMS 877
----------	-------------	------------	-----------	---------	----------	---------

color mechanical	date	initials	comments
Graphics			
Marketing			
Packaging Dev			
Legal			
Regulatory			
R&D			



DenTek www.DenTek.eu.com

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. Use only what is needed to repair the dental emergency, and save the rest for a future application. **Keep out of reach of children. Do not get into eyes.**

Tooth Saver: If tooth is dislodged, collect the tooth and do not try to clean it, there could be important soft tissue that will help in the healing process. 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.

Temparin[®] Max: 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. If irritation persists, inflammation develops, or if fever and infection develop stop use and ask a dentist or doctor.

Directions to replace a lost filling: Wash the cavity free with warm water to remove food particles. Saturate 1/3 of a fresh cotton swab applicator with liquid from the Eugenol vial and apply to tooth. Avoid touching surrounding gum tissue, cheek, or tongue with wet applicator tip. Do not leave applicator in mouth. The Eugenol will help the filling material set up and adhere to the tooth enamel. Cut with spade tool or pinch a small amount of Temparin[®] Max from the vial, and roll into a ball between fingers. Slightly overfill the cavity with Temparin[®] Max and tamp into place with applicator tool tip. Close your teeth together, as if you were biting down on a piece of paper, and gently chew or grind on the replaced filling a couple times to create a comfortable bite. Use a moist cotton swab to remove excess Temparin[®] Max from around the area. Moisture will accelerate the set. Temparin[®] Max 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 squarely back onto the tooth surface. If you are not able to do so, or if remaining tooth is cracked, then do not proceed further. If the crown has a post attached to it or if there is tooth surface remaining inside the crown, Temparin[®] Max may not adhere. Carefully rinse the tooth area and the inside of the crown, cap, or inlay with warm water, and do not dry. Cut with spade tool or pinch a small amount of Temparin[®] Max 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. Temparin[®] Max 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.

Ingredients for Temparin[®] Max: Zinc Oxide, Calcium Sulfate, Paraffinum Liquidum, Potassium Alum, Aluminium Sulfate, Aluminium Phosphate, Menthol, Eugenol, Iron Oxide Yellow

Ingredients for Eugenol: Eugenol, Sesame Oil

Questions or Comments www.DenTekUK.co.uk

EC REP Elara Pharmaceuticals Europe Ltd., 239 Blanchardstown Corporate Park, D15KX21, Ireland
MD Dentek Oral Care Limited, Clockhouse Court, 5-7 London Road, St Albans, Herts, AL1 1LA, UK (DKGB028801)
CE UK CA ©2021 Trade dress is owned by Dentek Oral Care Limited. All rights reserved.

6225005102270 0

EAN-13 UPC

DENTEK EUGENOL

eugenol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83062-400(NDC:60630-566)
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 (clear to pale yellow liquid with odor)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83062-400-21	1 in 1 KIT	10/10/2022	
1	NDC:83062-400-20	3.5 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	10/10/2022	

Labeler - IIMED MEDICAL MEXICANA S. DE R.L. DE C.V. (812894376)

Establishment

Name	Address	ID/FEI	Business Operations
IIMED MEDICAL MEXICANA S. DE R.L. DE C.V.		812894376	relabel(83062-400) , repack(83062-400)

Revised: 10/2022

IIMED MEDICAL MEXICANA S. DE R.L. DE C.V.