

## **DENTEK EUGENOL- eugenol liquid**

**DenTek Oral Care, 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.*

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### **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 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 ° F. Cap tightly to avoid evaporation.

**Outer Retail Package Label - DenTek Dental First Aid Kit**



3.878 in"

Tempain Max  
Made in Italy  
Eugenol Made in USA,  
Podagrin Made in USA  
1015-260940

**Drug Facts Eugenol**

**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).

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**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:** Adults and children 12 years 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 tissues other than the tooth cavity. Apply the drug not more than four times daily or as directed by a 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 10 years ask a dentist or doctor.

**Inactive ingredient:** sesame oil

**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 wiggly tooth in container making certain that milk or saliva is completely covering tooth. Contact your dentist immediately. Chances of successful reattachment are best if you see the dentist within 1 hour of incident.

**Tempain Max Lost Filling & Loose Cap Repair:** Tempain Max is designed to repair with the same ingredients dentists use. 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 with 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. 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 in eyes.

**Directions to replace a lost filling:** Wash the cavity area with warm water and do not dry. Cut with spade tool or pinch a small amount of Tempain Max from the vial, and roll into a ball between fingers. Slightly overfill the cavity with Tempain Max and temporarily place with applicator tool tip. Close your teeth together, as if you were biting down on a piece of paper, and gently chew. Grind on the replaced filling a couple times to create a comfortable bite. Use a moist cotton swab to remove excess Tempain Max from around the area. Moisture will accelerate the set. Tempain 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 accurately back into 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, Tempain Max may not adhere. Carefully rinse the both 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 Tempain 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. Tempain 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:** 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. Store at 68-77°F. Cap tightly to avoid evaporation.

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4.879"

**Project Name:** US DFAK (for tray)  
**Artwork Initiated:** 10/26/15  
**Artist:** LK  
**Supplier:** card pak  
**Require Addit. Vender Routing:** n

654C  
 2603C  
 + 4 color process  
 Back  
 Black

## DENTEK EUGENOL

eugenol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60630-566
<b>Route of Administration</b>	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: QX10HY4QV)	150 mg in 1 mL

### Product Characteristics

<b>Color</b>	yellow (Clear to pale yellow liquid, with odor of cloves)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60630-566-02	1 in 1 KIT	07/01/2015	
1	NDC:60630-566-01	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** - DenTek Oral Care, Inc. (153818646)

**Registrant** - DenTek Oral Care, Inc. (153818646)

### Establishment

Name	Address	ID/FEI	Business Operations
Polysciences, Inc.		014249635	manufacture(60630-566)

### Establishment

Name	Address	ID/FEI	Business Operations
DenTek Oral Care, Inc.		153818646	label(60630-566)

Revised: 12/2015

DenTek Oral Care, Inc.