# 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, persisitent 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 tissuers 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.

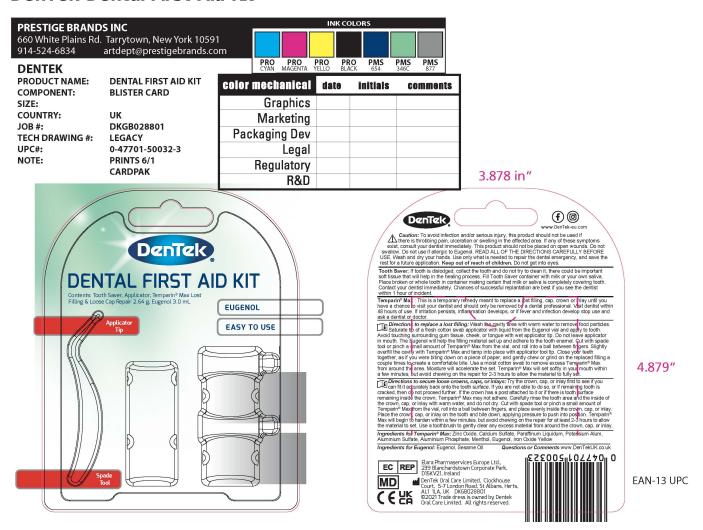
#### **Inactive ingredient**

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**



## **DENTEK EUGENOL**

eugenol liquid

Drod	IICT.	Intorr	nation
riuu	ucı		Hativii

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	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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)	