DENTEK EUGENOL- 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.

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 othere 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.

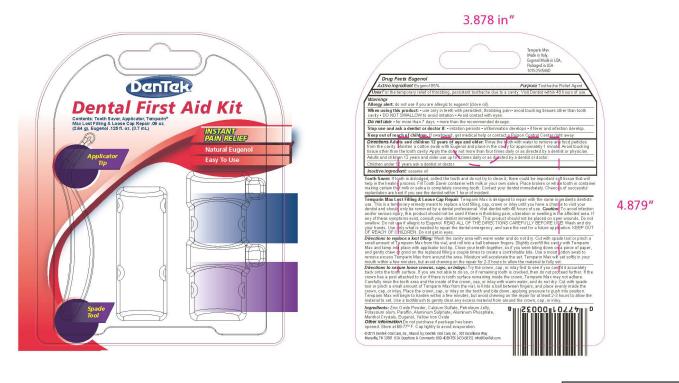
Adults and children 12 years and older use up to 4 times daily or as directed by a dentist or doctor.

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





DENTEK EUGENOL					
eugenol liquid					
Product Information					
Product Type	HUMAN OTC DRUG Item Code (Source			NDC:67659-400(NDC:60630-566)	
Route of Administration	DENTAL				
Active Ingredient/Active	Moiety				
Ingredie	ent Name		Basis	of Strength	Strength
EUGENOL (UNII: 3T8H1794QW) (EUGENOL - UNII:3T8H1794QW)			EUGENOL		850 mg in 1 mL
Inactive Ingredients					
Ingre	dient Name			Stre	ngth
SESAME OIL (UNII: QX10HYY4QV)			15	150 mg in 1 mL	

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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:67659- 400-21	1 in 1 KIT	07/01/2015		
	NDC:67659- 400-20	3.5 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product			
	400-20	Combination Product			
Marketing Information					
Maglasting Application Number of Magazine Maglasting Chart Maglasting Fad					

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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	relabel(67659-400) , repack(67659-400)	

Revised: 7/2022

Team Technologies, Inc