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.

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.

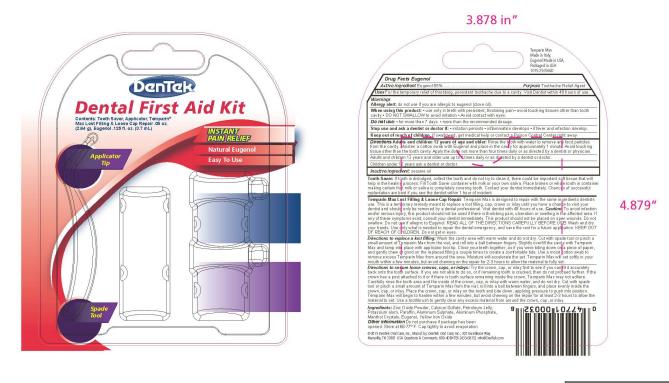
Adults and children 12 years and older use up to 4 times daily or as directed by a dentist or doctor.

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							
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Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:6		60630-566			
Route of Administration	DENTAL						
Active Ingredient/Active Moi	•						
Ingred	Basis of Strength		h	Strength			
EUGENOL (UNII: 3T8H1794QW) (EUG	EUGENOL		8	50 mg in 1 mL			
Inactive Ingredients							
Ing		Strength					
SESAME OIL (UNII: QX10HYY4QV)	150 mg in 1 mL						
Draduct Characteristics							
Product Characteristics							

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С	olor	yellow	Clear to pale yellow liquid, with odor of cloves)	Score			
S	Shape			Size			
F	lavor	vor			Imprint Code		
С	ontains						
Packaging							
#	Item Cod	le	Package Description	Marketing Start Date		Marketing End Date	
1	NDC:60630-56 02	66- 1	in 1 KIT	07/01/2015			
1	NDC:60630-56 01		7 mL in 1 VIAL, GLASS; Type 0: Not a Combination roduct				
Marketing Information							
	Marketing Ca	ategory	Application Number or Monograph Citation	Marketing Start D	ate	Marketing End Da	ate
0	TC monograph	not fina	nart356	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

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DenTek Oral Care, Inc.		153818646	label(60630-566)

Revised: 12/2015

DenTek Oral Care, Inc.