

EUGENOL - eugenol liquid
Polysciences, 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.

Eugenol**Active ingredients:**

Eugenol 85%

Purpose

Toothache Relief Agent

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.**Uses:**

For the temporary relief of throbbing, persistent toothache due to cavity. Visit Dentist within 48 hours of use.

Warnings For external use only. **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

• do not use for more than 7 days

• do not exceed recommended dosage

Stop use and ask a dentist or doctor if irritation persists, inflammation develops, or if fever and infection develop.

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 pellet with 1 to 2 drops of Eugenol and place in the cavity for approximately 1 minute. Avoid touching tissues other than the tooth cavity. Apply the dose 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 12 years ask a dentist or doctor.

Inactive ingredient

sesame oil

Questions or comments? 1-888-811-6188

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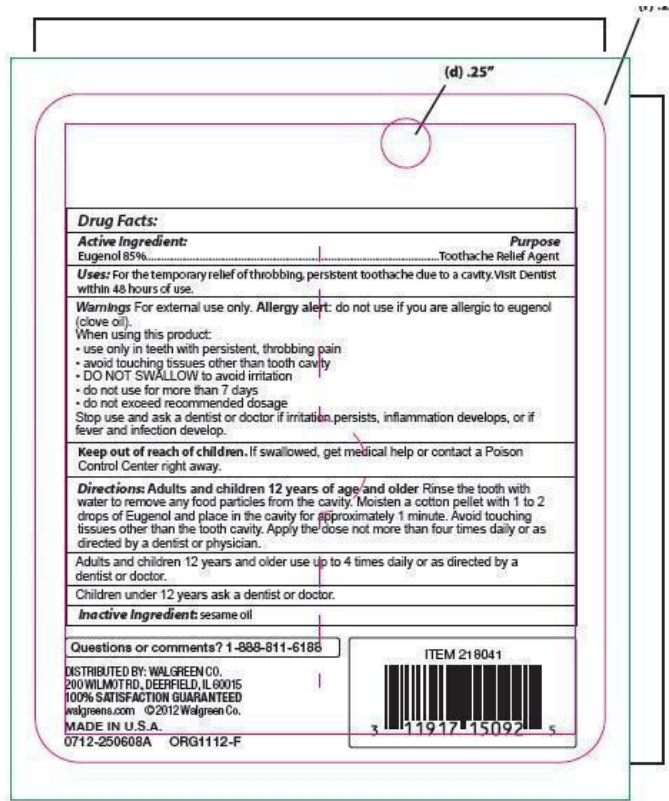
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MADE IN U.S.A

0712-250608A ORG1112-GF

Packaging



EUGENOL eugenol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61291-011
Route of Administration	ORAL	DEA Schedule	Å Å Å Å
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
EUGENOL (EUGENOL)	EUGENOL	850Å mg Å inÅ 1Å mL	
Inactive Ingredients			
Ingredient Name	Strength		
SESAME OIL	Å		
Product Characteristics			
Color	brown	Score	Å Å Å Å
Shape		Size	
Flavor		Imprint Code	
Contains	Å Å Å Å		
Packaging			
# Item Code	Package Description	Multilevel Packaging	
1 NDC:61291-011-04	3.7 mL in 1 VIAL, GLASS	None	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/30/2015	

Labeler -Â Polysciences, Inc (014249635)

Establishment

Name	Address	ID/FEI	Operations
Polysciences, Inc		014249635	manufacture

Revised: 12/2014^Â

Polysciences, Inc