RED CROSS TOOTHACHE- eugenol liquid The Mentholatum Company

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.

Drug Facts

Active ingredient

Eugenol 85%

Purpose

Toothache relief agent

Uses

temporarily relieves throbbing, persistent toothache due to a cavity until a dentist can be seen

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. Contact with lips or mucous membranes can cause burning, swelling, or irritation.
- 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

See a dentist as soon as possible whether or not the pain is relieved. Toothaches and open cavities indicate serious problems that need prompt attention by a dentist.

Keep Out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- rinse tooth with water to remove any food particles from the cavity
- using tweezers, immerse cotton pellet in medication
- to prevent dripping, squeeze gently between fingers to remove excess liquid
- place pellet in tooth cavity for *one minute***without touching surrounding tissues**, then remove
- supervise children using this product

adults and children 12 years and over: use up to 4 times daily or as directed by a dentist or doctor

children under 12 years: ask a dentist or doctor

Inactive Ingredients

sesame oil

Questions

1-877-636-2677 MON-FRI 9 AM to 5 PM (EST)

Package/Label Principal Display Panel



Principal Display Panel

USE ONLY IF BLISTER PACKAGE IS INTACT ÚSE ÚNICAMENTE SI EL EMPAQUE ESTA INTACTO

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Retain blistercard for full information. Conserve esta tarjeta informativa.

The Mentholatum Company Orchard Park, NY 14127 USA



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Información Farmacológica

Ingrediente activo: Eugenol 85% Propósito: Agente para aliviar el dolor de dientes. Uso: Para aliviar temporalmente el dolor de dientes punzante y persistente que se produce debido a una carie hasta ver un dentista. Precauciones: Sólo para uso externo. Alerta de alergia: No use este medicamento si es alérgico al eugenol (aceite de clavo). Cuando use este producto úselo solo en los dientes en que tenga un dolor punzante y persistente. Evite tocar otros tejidos además de la caries.

El contacto con los labios o membranas mucosas, puede causar ardor, inflamación o irritación. NO LO INGIERA para evitar irritación. No usar por más de 7 días. No exceda la dosis recomendada. Deje de usarlo y consulte a su dentista o doctor si persiste la irritación, o si desarrolla inflamación, fiebre o infección. Consulte un dentista tan pronto le sea posible aun cuando el dolor haya desaparecido. Dolor de dientes y caries abiertas indican problemas serios que deben ser tratados inmediatamente por un dentista, Mantenga el producto fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Sustancias Venenosas inmediatamente. Indicaciones: Enjuague el diente con agua para quitar todas las partículas de comida de la caries. Usando pinzas, sumerja una bola de algodón en el medicamento. Para prevenir goteo, presione suavemente con los dedos para eliminar excesivo de líquido. Coloque la bola del algodón en la caries por un minuto sin tocar los tejidos que rodean el diente. Supervise a los niños cuando usen este producto. Adultos y niños 12 años y mayores: úselo hasta 4 veces al día o le indique un dentista o doctor. Niños menores de 12 años: pregunte a un dentista o doctor, Ingrediente inactivo: Aceite de ajonjoli.

¿Preguntas? 1-877-636-2677 LUNES - VIERNES 9AM-5PM (HORA DEL ESTE)



RED CROSS TOOTHACHE

eugenol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10742-0009

Route of Administration TOPICAL

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)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:10742- 0009-1	1 in 1 BLISTER PACK	06/21/1983	
1	3.7 mL in 1 BOTTLE; 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	06/21/1983	
	part356	06/21/1983	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment				
Name	Address	ID/FEI	Business Operations	
The Mentholatum Company		002105757	manufacture(10742-0009)	

Revised: 2/2023 The Mentholatum Company