

MARSHALL TOOTHACHE DROPS- eugenol 85% (clove oil 2% v/v) solution/drops

Yashvire LLC

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.

MARSHALL TOOTHACHE DROPS

Drug Facts

Active Ingredient: Eugenol 85% (Clove Oil 2% v/v)

Purpose: Surface Anaesthetic

Uses: Acts as a surface anaesthetic temporarily relieving a 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 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 48 hours.
- Do NOT use more than the recommended dose.

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 for Use:

Adults and Children over 12 years:

- Rinse tooth with water to remove any food particles from the cavity
- Apply 1-2 drops to a piece of cotton wool
- Swab affected area with the cotton wool or plug into affected cavity
- Leave in tooth cavity for 1 minute without touching surrounding tissues, then remove and discard.
- Discontinue use if irritation occurs. Avoid contact with cheek, gums, palate and lips
- Supervise children using this product

Use up to 4 times daily or as directed by a dentist or doctor.

Other information. Do not purchase if package has been opened.

Store at 46 – 90 F. (8 – 32 °C). Cap tightly to avoid evaporation.

Inactive ingredients: Ethyl alcohol, Purified water, Carmoisine red dye

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Marshall Toothache Drops - 10 ml (0.33 fl.oz) - NDC 74094-002-01 - Carton



Marshall Toothache Drops - 10 ml (0.33 fl.oz) - NDC 74094-002-01 - Container



Traditional Healthcare

Toothache DROPS



Dosage: 1-2 drops applied to cotton wool Swab affected area or plug into tooth. Leave for a minute and then remove. For more info see enclosed leaflet.

Contains:
Eugenol 85%
(Clove Oil 2% v/v)

Manufactured in South Africa by **Marshall's**

Distributed by:
Yashvire LLC
13412 NW 38 Ct,
Opa Locka, FL,
USA, 33054
T: 646 969 2077
www.yashvire.com
NDC: 74094-002-01

10 ml (0.33 fl.oz)

MARSHALL TOOTHACHE DROPS

eugenol 85% (clove oil 2% v/v) solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74094-002
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUGENOL (UNII: 3T8H1794QW) (EUGENOL - UNII:3T8H1794QW)	EUGENOL	17 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	529 mg in 1 mL
WATER (UNII: 059QF0KO0R)	310 mg in 1 mL
CARMOISINE (UNII: DR4641L47F)	0.1 mg in 1 mL

Product Characteristics

Color	red (Clear red liquid with odour of clove oil)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74094-002-01	1 in 1 CARTON	05/17/2021	
1		10 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	05/17/2021	

Labeler - Yashvire LLC (117396744)

Registrant - MARSHALLS TRADITIONAL HEALTHCARE CC (637662219)

Establishment

Name	Address	ID/FEI	Business Operations
MARSHALLS TRADITIONAL HEALTHCARE CC		637662219	manufacture(74094-002) , pack(74094-002) , label(74094-002)

Revised: 5/2021

Yashvire LLC