

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Clove Oil BP.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clove Oil 100% v/v.

3. PHARMACEUTICAL FORM

Dental Solution

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the temporary relief of toothache.

4.2 Posology and method of administration

Dental use.

Adults, the elderly and children over 2 years old:

Apply a small amount on a cotton bud directly on the tooth cavity as required.

4.3 Contraindications

Hypersensitivity to clove oil, eugenol or Peru balsam.

Teething.

4.4 Special warnings and precautions for use

Use with caution in the mouth.

Avoid contact with the skin and gums.

Repeated use may cause gum damage.

Seek dental attention as soon as possible.

Not recommended for use in children under 2 years of age due to lack of adequate data.

4.5 Interaction with other medicinal products and other forms of interaction

May enhance inhibition of platelet activity in patients receiving anti-coagulant therapy e.g. warfarin.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Studies on the effects on fertility have not been performed.

4.7. Effects on Ability to Drive and Use Machines

None known.

4.8 Undesirable effects

Contact with skin or soft tissue may cause transient irritation, contact dermatitis, inflammation of the lips, and inflammation or ulceration of the mouth. The eugenol present in clove oil may act as an irritant to skin and mucous membranes; it may also cause hypersensitivity and is reported to inhibit prostaglandin synthesis. Patients may become sensitive to clove oil.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

No case of overdose from oromucosal or dental use has been reported.

After oral administration of 5-10 ml of clove oil in children below 2 years of age, life threatening conditions were observed. Adverse effects included coma, acidosis, a generalised seizure, disordered blood clotting, and acute liver damage.

Overdose may lead to CNS depression, urinary abnormalities, anion-gap acidosis, deterioration of liver function, coma, seizure and low blood glucose levels. Treatment should be supportive and symptomatic; there have been reports in the literature that N-acetylcysteine has been successfully used as an antidote.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Clove Oil has local anaesthetic, antiseptic and antihistaminic properties, and is used as an anodyne in toothache.

5.2. Pharmacokinetic Properties

Clove Oil acts at the site of application.

No data exists on the human pharmacokinetics of Eugenol the principle ingredient of Clove Oil.

In the rat 20-30% of Eugenol is metabolised to homovanillic acid and 4-hydroxy-3-methoxymandelic acid.

5.3. Pre-clinical Safety Data

None.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

None.

6.2. Incompatibilities

None known.

6.3. Shelf life

10ml: 36 months unopened.

6.4. Special Precautions for Storage

Store below 25°C.

Keep container tightly closed and protect from light.

6.5. Nature and contents of container

10ml: amber glass bottle with white plastic child resistant cap with EPE/Saranex liner.

6.6. Instructions for Use/Handling

None.

7 MARKETING AUTHORISATION HOLDER

L.C.M. Ltd.
Linthwaite Laboratories
Huddersfield
HD7 5QH
England.

8. MARKETING AUTHORISATION NUMBER(S)

PL 12965/0006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

25/08/1993 / 11/11/1998

10 DATE OF REVISION OF THE TEXT

10/09/2014