Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Teetha Chamomilla Teething Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chamomilla recutita 12c
Excipients with known effect
Ethanol
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral gel.
Colourless translucent gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of teething pain and the symptoms associated with teething which are sore & tender gums, flushed cheeks and dribbling.

4.2 Posology and method of administration

For babies aged 3 months and over.

With a clean finger apply a pea sized amount of gel to the sore area on the baby's gums and teeth.

Use every 4 hours for up to 6 times a day.

This product is not recommended for use in babies under 3 months old.

If symptoms worsen or persist after 7 days of using this product, a doctor or qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to Chamomilla preparations or any of the excipients listed in 6.1.

4.4 Special warnings and precautions for use

This medicine contains 21 mg of alcohol (ethanol) in each dose which is equivalent to 3.8 mg ethanol/kg body weight. The amount in one dose of this medicine is equivalent to less than 0.5 ml beer or 0.2 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

The use of this product with other medicinal products containing ethanol should be avoided.

Do not use if seal is broken.

A doctor or a qualified healthcare practitioner should be consulted if symptoms worsen or persist for more than 7 days.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

The use of this product in pregnancy and lactation is not applicable.

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. However, if use in pregnancy and lactation is required, the advice of a doctor should be sought.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

There are no known adverse effects. If any adverse effects are experienced, a doctor or pharmacist should be consulted.

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 of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance Website: www.hpra.ie.

4.9 Overdose

None known. Overdose with this medicine is unlikely to constitute a hazard and therefore symptomatic treatment only is necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water
Glycerol (E422)
Xanthan gum
Xylitol (E967)
Hypromellose
Ethanol anhydrous

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months
Once opened use within 28 days of opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Pack size 15g.
Collapsible, sealed aluminium tube with a polypropylene cap incorporating a tamper evident seal and a piercing device used to pierce the tube seal.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th April 2022

10 DATE OF REVISION OF THE TEXT

May 2022