Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Teetha Teething Granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 300mg granules in a sachet contain:

Chamomilla recutita (Chamomilla) 6C

Excipient(s) with known effects:
Lactose 60% w/w

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Granules
Fine white to off white granules

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 oral use

For babies aged 3 months and over

Detach one sachet from strip of 4.

Babies 3-6 months
With the baby upright or in a sitting position. Use a spoon. Slowly give the baby half a sachet at a time. The granules should be given slowly into the front of the baby's mouth a little at a time. Check all the granules have been fully dissolved before giving the remaining half.

Babies over 6 months
With the baby upright or in a sitting position slowly pour the contents of the sachet into the front of the baby's mouth a little at a time. Alternatively use a spoon. Ensure the granules fully dissolve in the baby's mouth.

Use one sachet every 2 hours for a maximum of 6 doses during any 24 hour period.

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 recutita or any of the excipients.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

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

This product is not recommended for use in babies under 3 months of age and medical advice should be sought.

Contains lactose - Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency of glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation: There is no evidence of the safety of the product in human pregnancy or lactation, nor is there any evidence from animal studies.
Although no adverse events have been observed, the use of this product during pregnancy and lactation should be avoided unless under the guidance of a doctor.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

Studies on the effects on the ability to drive or use machinery have not been performed.

4.8 Undesirable effects

None known
If any adverse reactions occur, 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, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No case of overdose has been reported.

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

Lactose
Xylitol (E967)
Maize Starch
Pregelatinised Maize Starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

24 or 40 Paper/Polyethylene/Aluminium foil/Polyethylene sachets packed in a cardboard carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 REGISTRATION HOLDER

Pharmaceutical Business Consultants Limited
Unit 4d
Western Business Park
Shannon
Clare
V14 RW92
Ireland

8 REGISTRATION NUMBER(S)

HOA23352/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th December 2017

Date of last renewal: 29th April 2022

10 DATE OF REVISION OF THE TEXT

October 2022