

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Teetha Teething Gel

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chamomilla recutita 12c

Aconitum napellus 12c

Atropa belladonna 12c

Excipients with known effect

Ethanol

For the 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, Aconite or Belladonna preparations or to any of the excipients listed in 6.1.

### 4.4 Special warnings and precautions for use

This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per dose.

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, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@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

### **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 and other handling**

No special requirements for disposal.

## **7 MARKETING AUTHORISATION HOLDER**

Nelsons GmbH  
Heegbarg 2  
22391 Hamburg  
Germany

## **7 REGISTRATION HOLDER**

Nelsons GmbH  
Heegbarg 2  
22391 Hamburg  
Germany

## **8 MARKETING AUTHORISATION NUMBER**

HOA22892/002/001

## **8 REGISTRATION NUMBER(S)**

HOA22892/002/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 16 November 2018

## **10 DATE OF REVISION OF THE TEXT**

December 2020