

IPAR



**Public Assessment Report for a
Homeopathic Medicinal Product
for Human Use**

HOA Holder

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I. INTRODUCTION

Specific provisions were introduced for homeopathic medicinal products (HMPs) in accordance with the Directive (2001/83/EC), as amended. The national regulations, the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) which implement this Directive came into force on 23rd July 2007. Consequently the HPRA has established the National Rules Scheme for Homeopathic Medicinal Products.

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of a homeopathic marketing authorisation for a specific homeopathic medicinal product for human use. It is made available by the HPRA for the purposes of providing information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of EC Directive 2001/83/EC, as amended by Directive 2004/27/EC and Directive 2004/24/EC. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA, leading to the approval of the homeopathic medicinal product for marketing in Ireland.

Based on the review of the data on quality, safety and homeopathic use, the HPRA has granted a homeopathic marketing authorisation for Teetha Teething Gel containing Aconitum napellus 12C, Atropa belladonna 12C and Chamomilla recutita 12C.

This application was submitted as a standard application according to Article 16.2 of Directive 2001/83/EC, as amended, and as part of the National Rules Authorisation Scheme.

The Summary of Product Characteristics (SmPC) for this homeopathic medicinal product is available on the HPRA's website.

II. QUALITY ASPECTS

Each 15g gel in a tube contains:

Aconitum napellus 12C

Atropa belladonna 12C

Chamomilla recutita 12C

(Full composition P1 below)

II.1 S.1 Homeopathic raw material

The homeopathic raw materials specifications for Aconitum napellus, Atropa belladonna and Chamomilla recutita are considered adequate to control the quality and meet current pharmacopoeial requirements. Batch analytical data demonstrating compliance with these specifications have been provided.

II.2 S.2 Homeopathic stock

The homeopathic stocks Aconitum napellus, Atropa belladonna and Chamomilla recutita, all have official monographs in an Official pharmacopoeia of a Member State, the German Homeopathic Pharmacopoeia, (GHP), and are manufactured in accordance with the principles of good manufacturing practice (GMP).

The homeopathic stocks specifications are considered adequate to control the quality and meet current pharmacopoeial requirements. Batch analytical data demonstrating compliance with these specification has been provided.

II.3 Medicinal product

P.1 Composition

Oral gel.

Teetha Teething Gel is a colourless translucent gel.

Composition of the medicinal product.

Chamomilla recutita 12c

Aconitum napellus 12c

Atropa belladonna 12c

Water

Glycerol (E422)

Xanthan gum
Xylitol (E967)
Hypromellose
Ethanol

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of GMP at suitably qualified manufacturing sites. The manufacturing process has been validated according to relevant European/ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients/*Ancillary Substances*)

All ingredients comply with Ph. Eur. or are adequately controlled by the manufacturer's specifications.

Adventitious agent safety

Teetha Teething Gel does not contain any ingredients of human or animal origin, therefore there is no risk from these agents in respect of this product.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for an Oral Gel and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported, where appropriate, by validation data.

Batch analytical data for a number of batches from the proposed production site(s) have been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 Packaging material

The product is presented as a 15g aluminium tube packaged in a cardboard carton.

Evidence has been provided that the container complies with EU legislation for use with foodstuffs requirements.

P.7 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines demonstrating the stability of the product for 2 years when stored at '*not above 25°C*', storage conditions of the SmPC.

II.4 Conclusion on quality

The important quality characteristics of the product are well-defined and controlled. Satisfactory pharmaceutical documentation has been provided, assuring consistent quality of Teetha Teething Gel.

III. NON-CLINICAL ASPECTS

The product Teetha Teething Gel is a homeopathic medicinal product as defined by Article 16 of Directive 2001/83/EC, as amended.

No preclinical studies have been submitted. This is acceptable for this type of application according to the regulations. The product Teetha Teething Gel conforms to subparagraph 11.3 of the regulations and therefore is deemed appropriate for the proposed use.

There are no safety issues with this product and bibliographic evidence has been provided to support 'Homeopathic Use', as required by the Directive 2001/83/EC, as amended.

Overall the information presented demonstrating homeopathic use is considered to be acceptable.

An environmental risk assessment is not required for homeopathic medicinal products as they contain highly dilute active ingredients and therefore pose no environmental risk.

IV. CLINICAL ASPECTS

This is a national application submitted by A Nelson and Co Limited under Article 16.2 of Directive 2001/83/EC, as amended. Teetha Teething Gel is a homeopathic medicinal product used for: *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.*

IV.1 Clinical efficacy

There is no requirement under the National Rules Scheme to prove scientifically that the product is efficacious, the authorisation is based exclusively upon the use of Teetha Teething Gel as a homeopathic medicine and not upon data generated from clinical trials.

Article 16. of Directive 2001/83/EC provides for Member States to introduce or retain in their territory specific rules for the toxicological and pharmacological tests and clinical trials of homeopathic medicinal products other than those referred to in Article 14(1) in accordance with the principles and characteristics of homeopathy as practised in the Member State.

Accordingly, the national regulations, the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) which implement this Directive lays down criteria under Article 11 whereby a homeopathic medicinal product may be authorised under the National Rules. With regard to homeopathic use data, the requirements of Article 11 have been met. The efficacy of this homeopathic medicinal product is plausible on the basis of use and experience.

The indication proposed for Teetha Teething Gel: *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*, is in line with homeopathic indications recorded and hence, compatible with the requirements of the regulations (S.I. No. 540 of 2007).

IV.2 Clinical Safety

In accordance with Article 11.3 the applicant has provided the relevant information.

There are no safety issues pertaining to the use of this product as proposed. In addition treatment is being recommended for a maximum of 7 days. This is in accordance with the use of the product for mild self-limiting conditions not requiring the intervention of a Medical practitioner. The warning '*If symptoms become worse or do not show improvement after 7 days, consult a doctor or qualified healthcare practitioner*', is present on the packaging.

Additionally the following are included on the SmPC, label and leaflet as appropriate.

Contraindications

Hypersensitivity to Chamomilla, Aconite or Belladonna preparations or to any of the excipients

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.

The safety of the homeopathic product has been demonstrated according to the criteria as laid down in Article 11.3 (S.I. No. 540 of 2007).

In conclusion, this product proves not to be harmful in the specified conditions of use based on the review of safety data and additional data provided.

IV.3 Pharmacovigilance

It should be noted that in accordance with Article 16 of Directive 2001/83/EC, as amended, the pharmacovigilance requirements described in Articles 101- 108 of Directive 2001/83/EC, as amended, also apply in respect of homeopathic medicinal products.

The Pharmacovigilance system as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

V. OVERALL CONCLUSIONS

The product Teetha Teething Gel is manufactured by Nelsons using the Pharmacopoeial (GHP) active ingredients, Aconitum napellus, Atropa belladonna and Chamomilla recutita and excipients according to Ph. Eur. Manufacturing processes are well described and controlled and appropriate for this type of oral gel homeopathic product. Production is carried out according to GACP/GMP as applicable.

The important quality characteristics of the product are well-defined and controlled. Satisfactory pharmaceutical documentation has been provided, assuring consistent quality of Teetha Teething Gel.

The product Teetha Teething Gel contains the active ingredients Aconitum napellus, Atropa belladonna and Chamomilla recutita which are controlled by monographs in the GHP. The actives are highly diluted to 12C in the finished product and adhere to the legislation with respect to safety requirements. All excipients in Teetha Teething Gel are Ph. Eur and appropriate for this type of medicinal product. Therefore this product is considered to be safe for use in accordance with the terms of Article 11 of S.I. 540 of 2007.

The product Teetha Teething Gel has been proposed as a treatment for teething: : *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.*

Homeopathic literature and provings support the use of the active ingredients Aconite napellus, Atropa belladonna and Chamomilla recutita for this indication. Since teething is considered to be a mild self-limiting condition it is suitable for treatment by this class of homeopathic product in accordance with the National Rules (S.I. 540 of 2007). In addition treatment is being recommended for a maximum of 7 days.

The HPRA, on the basis of the data submitted, considered that Teetha Teething Gel demonstrated adequate evidence of homeopathic use for the approved indication(s) and no new preclinical or clinical safety concerns have been identified. A homeopathic authorisation for Teetha Teething Gel is granted.

VI. REVISION DATE

December 2020

VII. UPDATES

Procedure number	Product Information affected	Date of start of procedure	Date of end of procedure	Approval/non approval
Transfer CRN009D4R	SmPC section 7, 8, 10 Package Leaflet New Registration Holder: Nelsons GmbH New HOA number: HOA22892/002/001	N/A	18/12/2020	Approved 18/12/2020