HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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

Colica Colic Granules

HOA1149/001/001
HOA holder: A Nelson & Company Limited

Date: 31.5.2019

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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 Colica Colic Granules, containing the actives substances: Citrullus colocynthis 30C and Dioscorea villosa 30C.

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.

QUALITY ASPECTS

This application is for Colica Colic Granules. The active ingredients of Colica Colic Granules are derived from Citrullus colocynthis and Dioscorea villosa plants.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 300mg granules in a sachet contains:

Citrullus colocynthis 30C

Dioscorea villosa 30C

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

(Full composition P1 below)

II.1 S.1 Homeopathic raw material

The homeopathic raw material specifications for both Citrullus colocynthis and Dioscorea villosa are considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.2 S.2 Homeopathic stock

The homeopathic stocks, Citrullus colocynthis and Dioscorea villosa, are both described in an Official pharmacopoeia of a Member State - Germany, the German Homeopathic Pharmacopoeia (GHP), and are manufactured in accordance with the principles of good manufacturing practice (GMP).

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

II.3 Medicinal product

P.1 Composition

Colica Colic Granules consists of white to off white oral granules in individual sachets.

Composition of the medicinal product.

Citrullus colocynthis 30C

Dioscorea villosa 30C

Lactose

Xylitol (E967)

Maize Starch

Pregelatinised Maize Starch

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

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies.

Scientific data have been provided for Colica Colic Granules and compliance with the *Note For Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products* has been satisfactorily demonstrated.

Adventitious viruses
See above

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for Oral Granules, 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 by validation data where relevant.

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 in a single dose sachet packaged in a carton of 12 or 24 sachets.

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

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 3 years when stored 'not above 25ºC', storage conditions of 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 Colica Colic Granules.

NON-CLINICAL ASPECTS

Colica Colic Granules 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 (S.I. 540 of 2007). The product Colica Colic Granules 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 as well as an Expert Report 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.

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.

Colica Colic Granules is a homeopathic medicinal product used for: "A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of colic in babies over one month of age".

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 Colica Colic Granules 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 Colica Colic Granules: *A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of colic in babies over one month of age*, 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 2 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 worsen or persist after 2 days of using this product, a doctor or qualified healthcare practitioner should be consulted, is present on the packaging.

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

Contraindications

Hypersensitivity to Citrullus colocynthis and Dioscorea villosa or any of the excipients.

Special warnings and precautions for use

Do not exceed the stated dose

If symptoms worsen or persist after 2 days of using this product, a doctor or qualified healthcare practitioner should be consulted.

This product is not recommended for use in babies under 1 months of age and medical advice should be sought.

The most common and distinctive symptom of colic is excessive crying in the baby that is otherwise healthy and well fed. If there is any doubt that the baby has colic, a doctor should be consulted as soon as symptoms first begin.

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

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, expert report 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.

OVERALL CONCLUSIONS

The product Colica Colic Granules is manufactured by Nelsons using the Pharmacopoeial (GHP) active ingredients Citrullus colocynthis and Dioscorea villosa and excipients according to Ph. Eur. Manufacturing processes are well described and controlled and appropriate for this type of oral 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 Colica Colic Granules.

The product Colica Colic Granules contains the active ingredients Citrullus colocynthis and Dioscorea villosa which are controlled by monographs in the GHP. The actives are highly diluted to 30C in the finished product and adhere to the legislation with respect to safety requirements. All excipients in Colica Colic Granules 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 Colica Colic Granules has been proposed as a treatment for Colic*: A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of colic in babies over one month of age*.

Homeopathic literature and provings support the use of the active ingredients Citrullus colocynthis and Dioscorea villosa for this indication. Since colic 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 2 days.

The HPRA, on the basis of the data submitted, considered that Colica Colic Granules demonstrated adequate evidence of homeopathic use for the approved indication and no new preclinical or clinical safety concerns have been identified.

A homeopathic authorisation for Colica Colic Granules is granted.

DATE OF APPROVAL

<Insert date>

REVISION DATE

<Insert date>

UPDATES

<Insert updates>