

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Colica Colic Granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 300mg granules in a sachet contain:

Citrullus colocynthis 30C

Dioscorea villosa 30C

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 colic in babies over one month of age.

4.2 Posology and method of administration

For oral use

For babies aged 1 months and over

Detach one sachet from strip of 4.

Babies 1-6 months

With the baby upright or in a sitting position, using 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 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 2 days of using this product, a doctor or qualified healthcare practitioner should be consulted

4.3 Contraindications

Hypersensitivity to Citrullus colocynthis and Dioscorea villosa 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 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.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

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

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

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

12 or 24 Paper/Polyethylene/Aluminium/Polyethylene sachets packed in a cardboard carton.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

There are no special precautions for disposal.

7 MARKETING AUTHORISATION HOLDER

A. Nelson & Company Limited
5-9 Endeavour Way
Wimbledon
London
SW19 8UH
United Kingdom

8 MARKETING AUTHORISATION NUMBER

HOA1149/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 31st May 2019

10 DATE OF REVISION OF THE TEXT