

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Neo Baby Gripe Mixture

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains Sodium Bicarbonate 50mg

Excipient(s) with known effect:

Strong Tincture of Ginger (contains ethanol)

Sucrose

Parahydroxybenzoates (methyl E218, ethyl E214, propyl E216 & butyl)

Propylene Glycol

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of wind pain and gripes.

4.2 Posology and method of administration

Posology

Paediatric population

For oral administration to infants and children

1 month up to 1 year:
5ml to be given three times a day as required.

Method of administration

Oral

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Parahydroxybenzoates (methyl E218, ethyl E214, propyl E216 & butyl) may cause allergic reactions (possibly delayed).

Patients with hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

The ingredient Strong Tincture of Ginger contains small amounts of ethanol (alcohol), less than 100mg per dose.

Propylene glycol may cause alcohol-like symptoms.

4.5 Interactions with other medicaments and other forms of interaction

None known.

4.6 Pregnancy and lactation

Can be given regularly to nursing mothers, pregnant women and adults suffering from wind pains.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

None known.

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 balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the yellow card scheme, website: www.mhra.gov.uk/yellowcard.

4.9. Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacids with sodium bicarbonate, ATC code: A02AH

Sodium Bicarbonate neutralises stomach acid and relieves dyspepsia.

5.2 Pharmacokinetic properties

The active is in solution and is available for direct action in the stomach and upper alimentary tract.

5.3. Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Strong Tincture of Ginger, Oil of Dill, Disodium Edetate, Sucrose, Soluble Saccharin, Parahydroxybenzoates (methyl E218, ethyl E214, propyl E216 & butyl), Propylene Glycol and Purified Water.

6.2 Incompatibilities

Not applicable.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Store below 25°C.

6.5. Nature and contents of container

Glass bottle (either Amber or White Flint) containing 150ml.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Neo Laboratories Ltd.
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Abingdon
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United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 02019/5001R

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF
AUTHORISATION**

6 August 1992

10 DATE OF REVISION OF THE TEXT

09/07/2015