

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Indian Brandee

Bell's Herbal Indigestion Remedy

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Co Rhubarb Tincture BP	5% v/v
Capsicum Tincture BPC	2.567% v/v
Glycerin BP	2% v/v

3. PHARMACEUTICAL FORM

Oral Solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of flatulence, heartburn and colic. The product is taken orally in warm water.

4.2 Posology and Method of administration

Oral.

Adults:

One to two 5ml spoonfuls.

Children 5 to 12 years:

Half to one 5ml spoonful in warm water as required.

Do not give to children under 5 years of age unless told by your doctor.

4.3 Contra-indications

Pregnancy and lactation.

Ileus.

Renal disorders.

4.4 Special warnings and special precautions for use

Keep out of reach of children.

Shake bottle.

If symptoms persist consult your doctor.

4.5 Interactions with other medicinal products and other forms of interaction

Not compatible with salicylates and ferrous sulphate.

4.6 Pregnancy and lactation

Data on a large number of exposed pregnancies indicate no adverse effects of Indian Brandee on pregnancy or on the health of the foetus/newborn child. To date, no other relevant epidemiological data are available. Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines

None known.

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 at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Although not to be expected unless the recommended dosage is grossly exceeded, treatment would be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Capsicum has a carminative action.

Rhubarb is a mild anthraquinone purgative exerting an astringent action after purgation.

Glycerin is demulcent and mildly laxative.

5.2 Pharmacokinetic properties

Little is published on the pharmacokinetics of the active ingredient of capsicum--capsaicin--or the ingredients of rhubarb which include glycosides, flavonoids, phenolic carboxylic acids and tannins.

Glycerin is readily absorbed from the gastro-intestinal tract and undergoes extensive metabolism in the liver. It may also be excreted unchanged in the urine.

5.3 Preclinical safety data

None available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose BP

Nipasept (parahydroxybenzoate esters)

Water

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months in unopened container.

6.4 Special precautions for storage

Store away from heat and direct sunlight at room temperature.

6.5 Nature and contents of container

Amber glass bottle with wadless plastic cap
Sizes 28 ml, 50 ml, 56 ml, 100 ml.

6.6 Instructions for use/handling

None.

7 MARKETING AUTHORISATION HOLDER

Bell, Sons & Co (Druggists) Ltd
Gifford House
Slaidburn Crescent
Southport
Merseyside
PR9 9AL

8. MARKETING AUTHORISATION NUMBER

PL 03105/0055

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of grant 18 August 1997
Date of renewal 16 April 1999

10. DATE OF REVISION OF TEXT

29/09/2015