

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Weleda Digestion Calming Drops.

2

QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml (corresponding to 0.91g) of oral liquid contains 0.37ml of liquid extract from:

Angelica root (*Angelica archangelica* L.) (equivalent to 11 mg Angelica root);

Cinnamon bark (*Cinnamom zeylanicum* Nees.) (equivalent to 15mg Cinnamon bark);

Nutmeg seed (*Myristica fragrans* Houtt.) (equivalent to 22mg Nutmeg seed); Melissa leaf (*Melissa officinalis* L.) (equivalent to 45mg Melissa leaf).

Extraction solvent: Ethanol 34% v/v

1 ml is equivalent to 20 drops.

1 ml of oral liquid contains approximately 485 mg of ethanol (alcohol) equivalent to 12.2 ml beer or 5.0 ml wine

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral drops, solution.
Clear, colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the symptomatic relief of nausea, stomach ache and upset stomach, based on traditional use only.

4.2 Posology and method of administration

For oral use.

Adults, the elderly and children over 12 years of age: 10-20 Drops in a little water every hour as required up to eight times a day; or as directed.

This product is not recommended for use in children under 12 years old. (See section 4.4, Special warnings and precaution for use.)

If the symptoms worsen or persist for longer than one week during the use of the medicinal product, a doctor or qualified healthcare practitioner should be considered.

4.3 Contraindications

Hypersensitivity to the active substance or to Peru balsam or to any of the excipients.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

This medicinal product contains 62% v/v ethanol (alcohol) ie up to 485 mg per dose (20 drops), equivalent to 12.2 ml beer, 5.0 ml wine per dose.

Harmful for those suffering from alcoholism. To be taken into account in pregnant, or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

The use of this product in children under 12 years of age is not recommended because data are not sufficient and medical advice should be sought.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronidazole).

4.6 Fertility, pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

No studies on the effect of the product on the ability to drive and use machines has been performed. Due to the presence of Melissa Leaf, this product may cause drowsiness. If affected do not drive or operate machines. Contains alcohol (see Section 2).

4.8 Undesirable effects

Local irritation of the oral mucosa has been reported with Cinnamon bark oil. The frequency is not known

If other adverse reactions do occur a doctor or qualified healthcare practitioner 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 balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

No case of overdose has been reported. Overdose of this product may result in alcohol intoxication. The amount in a full bottle [12.1g in 25ml and 24.2g in 50ml], is equivalent to 125/250 ml of wine or 305/610 ml of beer and may result in intoxication and should be treated accordingly.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16 c (1) (a) (iii) of Directive 2001/83 EC as amended

5.2 Pharmacokinetic properties

Not required as per Article 16 c (1) (a) (iii) of Directive 2001/83 EC as amended

5.3 Preclinical safety data

Tests on reproductive toxicity, genotoxicity and on carcinogenicity have not been performed.

Data from *in vitro* and animal studies indicate that the water extract of Melissa Leaf may inhibit the activity of thyroid stimulating hormone (TSH). The clinical relevance of these findings is not known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanolic distillate from Coriander and Clove
Lemon Oil
Ethanol
Purified Water

6.2 Incompatibilities

None Known

6.3 Shelf life

4 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

Amber glass bottle with white screw cap closure and dropper insert with tamper evident seal.
25ml and 50ml pack sizes

6.6 Special precautions for disposal

There are no special precautions for disposal.

7 MARKETING AUTHORISATION HOLDER

Weleda (UK) Ltd
Heanor Road
Ilkeston

Derbyshire DE7 8DR, UK

8 MARKETING AUTHORISATION NUMBER(S)

THR 00298/0289

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

29/04/2013

10 DATE OF REVISION OF THE TEXT

29/04/2013