# Weleda Digestion Calming Drops

**THR 00298/0289**  
**UKPAR**

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WELEDA DIGESTION CALMING DROPS

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Weleda (UK) Limited a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Weleda Digestion Calming Drops (Traditional Herbal Registration number: THR 00298/0289) on 29 April 2013. Weleda Digestion Calming Drops is available without prescription and can be bought from pharmacies and other outlets.

Weleda Digestion Calming Drops is a traditional herbal medicinal product used for the symptomatic relief of nausea, stomach ache and upset stomach, based on traditional use only.

This registration is based exclusively upon evidence of the use of Angelica root, Cinnamon bark, Nutmeg seed and Melissa leaf, as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
WELEDA DIGESTION CALMING DROPS

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Weleda Digestion Calming Drops (Traditional Herbal Registration number: THR 00298/0289) on 29 April 2013. This product is on the general sales list (GSL).

A product licence of right (PLR) was originally granted to Weleda (UK) Limited for this product. The PLR was reviewed and a product licence (PL 00298/5529R) was granted to Weleda (UK) Limited on 19 March 1992. Weleda (UK) Limited has committed to cancel PL 00298/5529R following the grant of the Traditional Herbal Registration Certificate.

This THR application was made under Article 16.c of Directive 2001/83 EC in accordance with arrangements to transfer certain herbal products with a Marketing Authorisation to a THR (according to MHRA Guidance dated January 2009). The application falls within the simplified THR application Category A, as no significant changes have been made to the formulation of the product. No new data were submitted, nor was it necessary for this application, as the data are essentially identical to those of the existing product.
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The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

**HERBAL PRODUCT:** WELEDA DIGESTION CALMING DROPS

**Description and Composition of the Herbal Product**
Weleda Digestion Calming Drops is a clear, colourless, oral drops solution. Each 1ml of oral liquid contains 0.37ml of liquid extract from:
Angelica root (equivalent to 11mg Angelica root), Cinnamon bark (equivalent to 15mg Cinnamon bark), nutmeg seed (equivalent to 22mg Nutmeg seed) and Melissa leaf (equivalent to 45mg Melissa leaf) and the pharmaceutical excipients ethanolic distillate from coriander and clove, lemon oil, ethanol and purified water. The formulation is in line with that of the already licensed product. It is, therefore, acceptable.

**Manufacture**
The manufacturing process is in line with that of the already licensed product and is satisfactory.

**Finished Product Specification**
The finished product specification is in line with that of the already licensed product and is satisfactory.

**Container Closure System**
Weleda Digestion Calming Drops is stored in amber glass bottles with white screw cap closure and dropper insert with tamper evident seal in pack sizes of 25ml and 50ml.
The packaging has been used to store the already licensed product and is satisfactory.

**Stability**
The product has a shelf-life of 4 years when the storage precautions ‘Do not store above 25°C’ and ‘Store in the original container’ are applied. This is in line with the already licensed product and is appropriate.

**Summary of Product Characteristics, product labels and Patient Information Leaflet**
All product literature is in line with that of the already licensed product, with some details amended in line with other products registered under the THR scheme.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.
ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
PRECLINICAL ASSESSMENT

INTRODUCTION
No new preclinical data have been supplied with this application and none are required for an application of this type.

Assurance has been given that the results of genotoxicity testing will be provided by the renewal date of the Traditional Herbal Registration.

PRODUCT LITERATURE
All product literature is satisfactory from a preclinical point of view.

ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
CLINICAL ASSESSMENT

INTRODUCTION
The clinical particulars for Weleda Digestion Calming Drops are identical to those for the already licensed product. This is satisfactory.

PRODUCT LITERATURE
All product literature is medically satisfactory.

ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
Weleda Digestion Calming Drops is identical to an already licensed product. It is, therefore, pharmaceutically satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type. The results of genotoxicity testing will be provided before the THR is renewed.

EFFICACY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products.

SAFETY
No new or unexpected safety concerns arose from this application.

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The benefit: risk balance is acceptable and a THR should be granted.
WELEDA DIGESTION CALMING DROPS

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STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Traditional Herbal Registration application on 13 July 2012
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 24 July 2012
3. A THR was granted on 29 April 2013
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 11mg Angelica root);

Cinnamon bark (*Cinnamomum 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 10 drops.

1 ml of oral liquid contains approximately 492 mg of ethanol (alcohol) equivalent to 12.24 ml beer or 4.4 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 984 mg per dose, equivalent to 24.8 ml beer, 8.8 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.

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 [12.28g in 25ml and 14.56g in 50ml], is equivalent to 129/258 ml of wine or 310/620 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
PATIENT INFORMATION

Read this leaflet carefully because it contains important information for you. Keep this leaflet. You may need to read it again.

Ask your pharmacist or qualified healthcare practitioner if you need more information or advice.

You must contact a doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after one week.

If any of the side-effects get serious, or if you notice any side-effect not listed in this leaflet, please tell your doctor or qualified healthcare practitioner.

In this leaflet:
1. What this product is and what it is used for
2. Before taking this product
3. How to take this product
4. Possible side-effects
5. How to store this product
6. Further information

1. What this product is and what it is used for

Weleda Digestion Calming Drops is a traditional herbal medicinal product used for the symptomatic relief of nausea, stomach ache and upset stomach. Based on traditional use only.

2. Before taking this product

Do not take Weleda Digestion Calming Drops if you are allergic to any of the ingredients or to Peru balsam (see Section 6). If you are pregnant or breastfeeding, or if you are taking any other medicines known to interact with alcohol eg. metronidazole.

- Special warnings and precautions for use:
  
  This medicinal product contains 62% v/v of ethanol (alcohol) i.e. up to 984mg per dose (before dilution). This is equivalent to 24.48ml of beer or 8.8ml of wine. This may be harmful for those suffering from alcoholism and should be taken into account in pregnant and breastfeeding women, children and high risk groups such as patients with liver disease and epilepsy.

- Driving and Using Machines

Weleda Digestion Calming Drops may cause drowsiness. If you are affected do not drive or use machinery.

3. How to take this product

Directions: Weleda Digestion Calming Drops are for oral use.

Adults, the elderly and children over 12 years of age:

Unless otherwise directed: 10-20 drops to be taken in a little water every hour as required up to 8 times a day.

Weleda Digestion Calming Drops is not recommended for children under 12 years of age.

DO NOT EXCEED THE STATED DOSE

If the symptoms worsen or persist after one week consult a doctor or qualified healthcare practitioner.
OVERDOSE
If you take too much of this product (overdose) this may result in alcohol intoxication and should be treated accordingly. See Section 2 - Special warnings and precautions for use. Consult your doctor or pharmacist and take this leaflet with you.

The amount in a full bottle of Weleda Digestion Calming Drops (12.28g in 25ml and 24.56g in 50ml), is equivalent to 110/220ml of wine or 306/612ml of beer.

WHAT TO DO IF YOU MISS A DOSE
If you miss a dose of Weleda Digestion Calming Drops, just take the next dose. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side-effects
Weleda Digestion Calming Drops may cause mouth irritation.
If you experience any unwanted effects consult your doctor, pharmacist or qualified healthcare practitioner.
You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your GP’s surgery or pharmacy, or call freephone 0808 100 3352 (available 10am-2pm Monday - Friday).

5. How to store this product
- keep out of the reach and sight of children
- do not store above 25°C
- do not use after the expiry date on the carton
- store in the original container
- return any unused medicine to your pharmacist for safe disposal

6. Further Information
Each ml (corresponding to 0.91g) of Weleda Digestion Calming Drops contains 0.37ml of liquid extract from: Angelica root (Angelica archangelica L.) (equivalent to 11mg Archangelica root); Cinnamon bark (Cinnamomum 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.
The other ingredients are: Ethanolic distillate from Coriander and Clove; Lemon oil; Ethanol; Purified Water.

Pack Description: Weleda Digestion Calming Drops are clear, colourless oral drops presented in an amber glass bottle. Each bottle contains 25ml or 50ml. Not all pack sizes may be marketed.

THR holder and manufacturer: Weleda (UK) Ltd., Heanor Road, Ilkeston, Derbyshire DE7 8DR, UK.
THR 00298/0289.

Braille version
To request a copy of this leaflet in Braille or large print, or to listen to an audio version, please call free of charge: 0800 198 5000 (UK only). Please be ready to give the following information:
Product name: Weleda Digestion Calming Drops.
Reference number THR 00298/0289.
This service is provided by the Royal National Institute for Blind people.

Leaflet last revised May 2013