Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Digestisan oral drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (20 drops) of oral liquid contains:

- 218 mg of tincture from fresh *Cynara scolymus* L., folium (Artichoke leaves), (1:30-31). Extraction solvent: ethanol 65% v/v.
- 218 mg of tincture from fresh *Taraxacum officinalis* Weber, radix cum herba (Dandelion root and herb), (1:17-18). Extraction solvent: ethanol 51% v/v.
- 34 mg of tincture from *Peumus boldus* Molina, folium (Boldo leaves), (1:10-11). Extraction solvent: ethanol 70% v/v.
- 15 mg of tincture from fresh *Mentha x piperita* L., herba (Peppermint herb), (1:18-19). Extraction solvent: ethanol 65% v/v.

Ethanol content: 60% v/v

1 ml is equivalent to 38 drops.

Excipients with known effect:
One dose (20 drops) of oral liquid contains 255 mg of ethanol (alcohol).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral drops, solution (oral drops).
It is a brown clear liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Traditional herbal medicinal product for the symptomatic relief of digestive disorders such as indigestion, feelings of fullness and flatulence exclusively based on long-standing use.

This product is indicated for use in adults.

4.2 Posology and method of administration

Posology
Adults (18 years and over): 15-20 drops 3 times daily

This product is not indicated in patients less than 18 years.

If the condition worsens or symptoms do not improve after 1 week, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Method of administration
For oral short-term use only.

4.3 Contraindications

Hypersensitivity to Artichoke, Dandelion, Boldo or Peppermint preparations or to any of the excipients listed in section 6.1.

Do not use in cases of known hypersensitivity to plants of the Asteraceae (Compositae) family or to menthol.

Do not use in cases of bile duct obstruction, cholangitis, liver disease, gallstones and any other biliary disorders.

Pregnancy and lactation (See also sections 4.6 and 5.3).

4.4 Special warnings and precautions for use

Do not exceed the recommended dose.

Patients with gastro-oesophageal reflux (heartburn) should avoid taking the product as heartburn may increase due to the peppermint leaf.

Patients with renal failure and/or diabetes, and/or heart failure should avoid taking the product because of possible complications due to hyperkalaemia.

If the condition worsens or symptoms do not improve after 1 week, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

This medicinal product contains 60 % vol ethanol (alcohol), ie up to 255 mg per 20 drop dose (187 mg/15 drops), equivalent to 6.4 ml beer (4.6 ml/15 drops) or 2.7 ml wine (1.9 ml/15 drops) 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.

Use in children and adolescents under 18 years of age is not recommended because data are insufficient and medical advice should be sought.

4.5 Interaction with other medicinal products and other forms of interactions

Limited data on pharmacological interactions with other medicinal products are available. Clinically relevant interactions with drugs metabolized by the CYP 2D6, CYP 3A4/5, CYP 1A2 or CYP 2E1 pathway have not been observed.

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

There are no or limited amount of data from the use of Digestisan in pregnant women. Studies in animals with an ethanolic extract of boldo leaf and boldine have shown reproductive toxicity (see section 5.3). Digestisan is not recommended during pregnancy and in women of childbearing potential not using contraception.

There is insufficient information on the excretion of Digestisan/metabolites in human milk. A risk to newborn/infants cannot be excluded. Digestisan should not be used during breast-feeding.

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 on the ability to drive and use machines have been performed.

This product contains alcohol (See Section 4.4 for details of alcohol content). Overdose of this product may result in alcohol intoxication.

4.8 Undesirable effects

Hypersensitivity reactions have been reported including reports of anaphylaxis with products containing Boldo.

Epigastric pain, hyperacidity and mild gastrointestinal symptoms (e.g. flatulence) may occur. Gastro-oesophageal reflux may worsen and heartburn may increase.

The frequency is not known.

If other adverse reactions not mentioned above occur, a qualified healthcare professional e.g. 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 balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA 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

Overdose of this product may result in alcohol intoxication. The amount of alcohol in a full bottle is:
- 7.2 g in 15 ml (equivalent to less than 1 small glass of wine)
- 14.4 g in 30 ml (equivalent to 1 small glass of wine)
- 24 g in 50 ml (equivalent to 1 large glass of wine)

Overdose may result in intoxication and should be treated accordingly.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

No mutagenic effects of Digestisan were detected in Ames' test (with or without metabolic activation). Tests on reproductive toxicity have been performed with a dry ethanolic extract of boldo leaf and boldine administered orally to pregnant rats. Results showed anatomical alterations in the foetus and a few cases of abortion at high doses.

Tests on reproductive toxicity and carcinogenicity have not been performed with this product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Brown glass dropper bottles (Type III glass) with a two part dropper (low density polyethylene)/dispenser cap (polypropylene) and ring (high density polyethylene).

Pack sizes: 15 ml
30 ml
50 ml

Brown glass dropper bottles (Type III glass) with a two part dropper (low density polyethylene)/child-resistant closure (high density polyethylene/high density polyethylene).
Pack sizes: 15 ml
30 ml
50 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 REGISTRATION HOLDER

A. Vogel Ireland Limited
48 Upper Drumcondra Road
Dublin 9
Ireland

8 REGISTRATION NUMBER(S)

TR2309/007/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 7th of February 2014
Date of last renewal: 6th February 2019

10 DATE OF REVISION OF THE TEXT

May 2019