Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Artichoke-Milk Thistle Complex Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

- 4.6 mg (as dry extract) *Cynara scolymus* L., folium (Artichoke leaves) (1:30-31), extraction solvent: ethanol 65% v/v.
- 3.2 mg (as dry extract) *Silybum marianum* (L.) Gaertn. fructus (Milk Thistle fruit) (1:2.0-2.1), extraction solvent: ethanol 58% v/v.
- 1.2 mg (as dry extract) *Taraxacum officinalis* Weber, radix cum herba (Dandelion root and herb) (1:17-18), extraction solvent: ethanol 51% v/v.
- 0.7 mg (as dry extract) *Peumus boldus* Molina, folium (Boldo leaves) (1:10-11), extraction solvent: ethanol 70% v/v.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets
Beige-coloured, round biconvex tablets

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): Take 1 tablet twice a day.

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. doctor or pharmacist should be consulted.

Method of administration
For oral short-term use only.

4.3 Contraindications

Do not use in cases of known hypersensitivity to Artichoke, Dandelion, Boldo or Milk Thistle 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.

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

Patients suffering from active liver disease should consult their doctor before taking the product.

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.

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 interaction

Limited data on pharmacological interactions with other medicinal products are available.

In vitro Milk Thistle extract resulted in inhibition of CYP isoenzymes. However the clinical relevance of these findings is not known.

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of Artichoke-Milk Thistle Complex in pregnant women. Studies in animals with an ethanolic extract of Boldo leaf and boldine have shown reproductive toxicity (see section 5.3). Artichoke-Milk Thistle Complex should not be used during pregnancy and in women of childbearing potential not using contraception.

There is insufficient information on the excretion of Artichoke-Milk Thistle Complex/metabolites in human milk. A risk to newborn/infants cannot be excluded. Artichoke-Milk Thistle Complex 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.

4.8 Undesirable effects

Hypersensitivity reactions have been reported including asthma and anaphylaxis.

Mild gastrointestinal symptoms such as dry mouth, nausea, diarrhoea with abdominal spasm, abdominal pain, hyperacidity, and heartburn have been reported.

Headaches and skin hypersensitivity reactions (dermatitis, urticaria, skin rash, pruritis) have also been reported.

The frequency is not 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 HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

No case of overdose has been reported.

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

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

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 fetus and a few cases of abortion at high doses.

No mutagenic effects of Artichoke-Milk Thistle Complex were detected in the Ames' test (with or without metabolic activation).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Hydrogenated cottonseed oil

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

Amber glass bottle (Ph. Eur. type III), coated aluminium sealing foil and aluminium pilfer-proof closure fitted with a polyethylene liner.

Pack size: 60 tablets

6.6 Special precautions for disposal and other handling

No special requirements.

7 REGISTRATION HOLDER

A.Vogel Ireland Limited
Unit 3d
Killeen Road
Dublin 10
D10 TY20
Ireland

8 REGISTRATION NUMBER(S)

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 25th July 2014

Date of last renewal: 24th July 2019

10 DATE OF REVISION OF THE TEXT

December 2022