SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

A.Vogel Milk Thistle Complex tablets

Digestisan Milk Thistle tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets
Beige-coloured, round, biconvex tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for indigestion, sensation of fullness and flatulence associated with over-indulgence of food or drink, or both, based on traditional use only.

4.2 Posology and method of administration

For oral use only.

Adults and the elderly (18 years and over): Take 1 tablet twice a day.

If symptoms worsen or do not improve after 2 weeks a doctor or qualified healthcare practitioner should be consulted.

Not for children or adolescents under 18 years (see also 4.4 Special warnings and precautions for use).

4.3 Contraindications

Hypersensitivity to any of the active substances or to plants of the Asteraceae (Compositae) family or to any of the excipients.

Patients with:
- obstruction of the bile duct or intestinal tract,
- cholangitis,
- liver disease including hepatitis,
- gallstones, active peptic ulcer and any other biliary disorders

4.4 Special warnings and precautions for use

Do not exceed stated 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 does not improve after two weeks, consult a doctor or a qualified healthcare practitioner.

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

None reported.

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

The safety of this product during pregnancy and lactation has not been established.

In view of the pre-clinical safety data (see section 5.3) the use of this product during pregnancy and lactation is not recommended.

Studies 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 and allergic reactions have been reported including reports of anaphylaxis with products containing Boldo.

Mild gastrointestinal symptoms such as nausea, diarrhoea with abdominal spasm, abdominal pain, hyperacidity and heartburn, headache and allergic reactions (urticaria, skin rash, pruritis, anaphylaxis) may occur.

The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a 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 at: www.mhra.gov.uk/yellowcard.

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, genotoxicity 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 rates.

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 (type III glass conforming to Ph.Eur. standards), coated aluminium sealing foil and aluminium pilfer proof cap fitted with a polyethylene liner.

Pack sizes: 60 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

THR 13668/0028

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25/02/2013

10 DATE OF REVISION OF THE TEXT

23/06/2020