SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

DigestEeze Milk Thistle Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 137.5mg – 165mg of standardised extract (as dry extract) from Milk Thistle fruits (*Silibum marianum* (L) *Gaertner*), (equivalent to between 2750mg and 6600mg of Milk Thistle fruits) corresponding to 82.5mg Silymarin calculated as Silibinin.

Extraction solvent: ethyl acetate 100% v/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets

A yellow – yellow/brown oval bi-convex uncoated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used to relieve the symptoms associated with occasional over indulgence of food and drink such as indigestion and upset stomach based on traditional use only.

4.2 Posology and method of administration

For oral use only.

Adults and the elderly: take 1 – 2 tablets twice daily. Swallow the tablet(s) whole with some liquid.

This product is not recommended for use in children or adolescents under 18 years of age (See Section 4.4. Special warnings and precautions for use)

If the condition worsens, or symptoms persist, a doctor or qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to the active substance or other members of the Asteraceae /Compositae family or any of the excipients

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

The use of this product in children and adolescents under 18 years of age is not recommended as there is no relevant indication.

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

Milk Thistle may alter the way certain drugs are broken down by the liver (see Section 4.5 'Interaction with other medicinal products and other forms of interaction')

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

The safety of the product during pregnancy has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. Animal studies are insufficient with respect to reproductive toxicity (see Section 5.3)

Studies on the effects of 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

Gastointestinal reactions (nausea, upset stomach, diarrhoea), headache, allergic reactions (urticaria, skin rash, pruritis, anaphylaxis).

The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or qualified healthcare practitioner should be consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after registration 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.

Supportive and symptomatic treatment should be provided as appropriate.

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

In the mouse, the acute oral toxicity of silymarin in milk thistle extracts was found to be in excess of 2000mg/kg. No deaths occurred within 48 hours of administration. In the rat, repeated oral administration of 1000 mg/kg/day for 15 days or 100mg/kg for 16 or 22 weeks showed no adverse effects when compared with controls. In a separate study, repeated oral administration of 1050, 2180, or 4500 mg/kg/day caused reductions in sperm motility and the number of spermatid heads per testis by up to 11% and 21% respectively. However, the observed effects were not associated with any histopathological findings and were not evident in mice following repeated oral administration of up to 11620 mg/kg for 3 months. Following repeated oral administration of silymarin to pregnant rats (at 1000 mg/kg/day from day 8 to day 12 of gestation) and rabbits (at 100mg/kg from day 8 to day 17), no embryotoxic effects were evident on day 21 of pregnancy.

Milk Thistle extract was considered to be mutagenic in the TA98 strain (but not the TA100, TA1535, TA1537 and TA102 strains) of *S typhimurium.* It was also considered to be mutagenic in a mammalian chromosomal aberration assay at the maximum concentration evaluated (240 mcg/mL).However, it was not mutagenic in an in vivo chromosomal aberration assay at a dose that was substantially (47-fold) higher than the maximum proposed clinical dose of 522 mg or 10.4 mg/kg/day. In addition, no indication of carcinogenic potential was observed during two-year studies in the mouse or rat following repeated oral administration of up to 7180 or 2750 mg/kg/day, respectively.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate anhydrous

Cellulose microcrystalline

Silica colloidal hydrated

Croscarmellose sodium

Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25^0C. Store in the original package

6.5 Nature and contents of container

Ph Eur type III glass bottles with polypropylene cap incorporating an induction heat seal liner. Printed outer carton containing Patient Information Leaflet.

Pack sizes: 30, 60, 90, 120 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)

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/03/2012

10 DATE OF REVISION OF THE TEXT

14/04/2016