Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Holland & Barrett Milk Thistle Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 133 mg – 324 mg of extract (as dry extract) from *Silybum marianum* L. Gaertn, fructus (milk thistle fruit) (equivalent to 3325 – 9720 mg of milk thistle fruit) corresponding to 108 mg of silymarin, calculated as silibinin.

Extraction solvent: Acetone 99.9% v/v.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Capsules, hard
A two piece clear, hard capsule with a beige / brown fill.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A 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.

4.2 Posology and method of administration

For oral short-term use only.
This product is not indicated in patients less than 18 years of age

Adults and the elderly
Take 1 capsule 2 times daily. Swallow the whole capsule with water.

Do not exceed the stated dose.

Duration of use:
If symptoms worsen or do not improve after 1 weeks use of Holland & Barrett Milk Thistle Hard Capsules, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

The safety of Milk Thistle in children and adolescents under 18 years of age has not been established as no data are available.

4.3 Contraindications

- Do not use in cases of known hypersensitivity to Milk Thistle or to plants of the Asteraceae (Compositae) family or to any of the excipients in Holland & Barrett Milk Thistle Hard Capsules
- Patients under 18 years of age
- Pregnancy and lactation

4.4 Special warnings and precautions for use

- Do not exceed the stated dose
- Patients suffering from active liver disease should consult their doctor before taking the product

- Milk Thistle may alter the way that certain drugs are broken down by the liver (see Section 4.5 Interaction with other medicinal products and other forms of interaction)
- Use in children and adolescents under 18years of age is not recommended because data are insufficient and medical advice should be sought.
- 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.

4.5 Interaction with other medicinal products and other forms of interactions

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 and lactation has not been established. Therefore, Holland & Barrett Milk Thistle Hard Capsules should not be used during pregnancy and lactation.

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. If affected patients should not drive or use machinery.

4.8 Undesirable effects

- Gastrointestinal disorders such as nausea, upset stomach, diarrhoea,
- Central Nervous system disorders such as headache
- Anaphylaxis (a sudden, severe allergic reaction with swelling and breathing difficulties)
- Allergic skin reactions such as urticarial, skin rash, pruritus

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

There are no data on human overdose with Milk Thistle. Symptomatic and supportive measures should be taken as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Non-clinical pharmacokinetic studies have not been conducted.

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

Milk Thistle extract was not mutagenic in an in-vivo mammalian murine micronucleus test. Adequate tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Magnesium stearate
Silica, colloidal hydrated

Inactive ingredients (excipients) in the dry extract:
Maltodextrin

Capsule Shell
Hypromellose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.
Keep the bottle tightly closed in order to protect from light and moisture.

6.5 Nature and contents of container

Green polyethylene terephthalate (PET) bottles with a polypropylene cap and an inner seal liner made up of polyester, polymer adhesive layer, polyolefin foam and aluminium foil.

Pack sizes: 30 capsules and 50 capsules.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Holland & Barrett Limited
Cedar Drive
Dublin Airport Logistics Park
Saint Margarets
Co Dublin
K67 E0C5
Ireland

8 REGISTRATION NUMBER(S)

TR23157/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th September 2014
Date of last renewal: 25th September 2019

10 DATE OF REVISION OF THE TEXT

February 2021