

SUMMARY OF PRODUCT CHARACTERISTICS**1 NAME OF THE MEDICINAL PRODUCT**

Digestherb hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

400mg of extract (as dry extract) from Artichoke leaf (*Cynara scolymus* L.)
(equivalent to 1600-2400 mg of dry herb.

Extraction solvent: Water.

Each capsule contains 85 mg lactose.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Hard gelatin capsule

Green, opaque.

4 CLINICAL PARTICULARS**4.1 Therapeutic indications**

Traditional herbal medicinal product used for the relief of digestive complaints, such as indigestion, upset stomach, , nausea, feelings of fullness and flatulence (wind), particularly caused by over indulgence of food and drink, based on traditional use only.

4.2 Posology and method of administration

For oral use only. The patient should be advised to consult a doctor if symptoms do not improve after 1 week.

For adults and the elderly, take one capsule twice daily. The capsules should be swallowed whole with a little liquid before food.

Not for use in children and adolescents under 18 years.

4.3 Contraindications

Hypersensitivity to Artichoke or any of the other ingredients in the product.

Patients with gall stones or with a history of obstructive gall bladder disease.

Not recommended for use in children or adolescents under 18 years of age, or in pregnancy, or in lactation (see section 4.6).

4.4 Special warnings and precautions for use

This product contains lactose:
1 capsule contains max. 85 mg lactose.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

There are no published data available on drug interactions with extracts of artichoke leaf.

4.6 Pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established, therefore it should be avoided during pregnancy or while breast-feeding.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Undesirable effects associated with the use of artichoke leaf extract are generally mild and self limiting. The following undesirable effects have been reported in clinical studies:

Nausea
Increased flatulence
Diarrhoea
Asthenia

4.9 Overdose

In the event of an overdose, patients are advised to contact a doctor, pharmacist or healthcare professional. A small overdose (up to 8 capsules) may not cause any symptoms. In the event of a large overdose (more than 8 capsules), advice should be sought from a doctor.

Management of an overdose should include appropriate symptomatic and supportive treatment as warranted by the clinical situation.

5 PHARMACOLOGICAL PROPERTIES

5.1 *Pharmacodynamic properties*

No pharmacodynamic studies have been undertaken with Digestherb, the pharmacodynamic properties are unknown.

5.2 *Pharmacokinetic properties*

No pharmacokinetic studies have been conducted with Digestherb or its active constituents.

5.3 *Preclinical safety data*

The non-clinical toxicology data available are limited. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 *List of excipients*

Extract excipients:

Lactose monohydrate
Silica, colloidal anhydrous

Other excipients:

Talc
Magnesium stearate
Silica, colloidal anhydrous
Maize starch
Lactose monohydrate
Gelatin
Titanium dioxide E171
Sodium lauryl sulfate
Iron (III)-oxide E172 (=red iron oxide)
Iron oxide hydrate E172 (=yellow iron oxide)
Chlorophyllin copper complex E141

6.2 *Incompatibilities*

Not applicable

6.3 *Shelf life*

The shelf life is 30 months

6.4 *Special precautions for storage*

Do not store above 25°C.

6.5 *Nature and contents of container*

Original packages containing 30, 60 or 90 capsules

Digestherb capsules are packed in PVC/PVDC- aluminium blisters and inserted into a carton.

6.6 *Special precautions for disposal*

No special requirements

7 **MARKETING AUTHORISATION HOLDER**

Schwabe Pharma (UK) Ltd
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8 **REGISTRATION NUMBER**

THR 23056/0005

9 **DATE OF FIRST REGISTRATION**

To be advised.

10 **DATE OF REVISION OF THE TEXT**