

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Hypromellose (capsule shell)

### 6.2 Incompatibilities

Not Applicable.

### 6.3 Shelf-life

2 years.

### 6.4 Special Precautions for storage

Store below 25°C in the original package.

### 6.5 Nature and contents of container

Duma 110ml HDPE plastic container and tamper evident threaded Duma cap.

Duma 200ml HDPE plastic container and tamper evident Duma cap.

SILAMARIE pack contains 60 or 120 Capsules.

### 6.6 Special precautions for disposal

There are no special precautions for disposal.

## 7 MARKETING AUTHORISATION HOLDER

Bio-Health Limited  
Culpeper Close  
Medway City Estate  
Rochester  
Kent  
ME2 4HU

## 8 MARKETING AUTHORISATION NUMBER(S)

THR 15817/0009

## 9 DATE OF REGISTRATION

13/12/2011

## 10 DATE OF REVISION

13/12/2011



# Silamarie<sup>®</sup>

## SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

## 1 NAME OF THE MEDICINAL PRODUCT

SILAMARIE

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 450mg of Milk Thistle fruits (*Silybum marianum* L. Gaertner)

For full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Hard capsules.  
Clear size 0 hard capsules.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

SILAMARIE is 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 or 2 capsules 3 times daily swallowed with water up to a maximum of 6 capsules daily.

Duration of use:-  
If the condition worsens or symptoms persist, a doctor or a qualified healthcare practitioner should be consulted.

This product is not recommended for children or adolescents under 18 years of age (see Section 4.4 Special Warnings and Precautions for Use).

### 4.3 Contra-indications

Hypersensitivity to Milk Thistle 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 is not recommended in children and adolescents below the age of 18 years as there is no relevant indication

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 medicine).

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

## 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 Pregnancy and Lactation

The safety of SILAMARIE during pregnancy and lactation has not been established.  
Due to the lack of sufficient data, use during pregnancy and lactation is not recommended.

Studies on fertility have not been carried out.

## 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

Gastrointestinal 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 a qualified healthcare practitioner should be consulted.

## 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

Test on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.