

## NATURAL HEALTH PRODUCT MILK THISTLE- *SILYBUM MARIANUM*

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

### Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

**Date** August 28, 2018

### Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Silybum marianum</i>	<ul style="list-style-type: none"> <li>▶ Blessed milk thistle</li> <li>▶ Gundagai thistle</li> <li>▶ Holy thistle</li> <li>▶ Lady's thistle</li> <li>▶ Mary's thistle</li> <li>▶ Mary thistle</li> <li>▶ Milk thistle</li> <li>▶ St. Mary's thistle</li> <li>▶ Variegated thistle</li> </ul>	<i>Silybum marianum</i>	<ul style="list-style-type: none"> <li>▶ Fruit</li> <li>▶ Seed</li> </ul>	Dried

References: Proper name: USDA 2018; Common names: USDA 2018, McGuffin et al. 2000; Source materials: Barnes et al. 2007, Bradley 2006, Mills and Bone 2005, Blumenthal et al. 2000.

### Route of administration

Oral

### Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.



Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

### Note

Due to poor water solubility of silymarin, infusions and decoctions are not permitted for “hepatoprotectant/liver protectant and/or support of liver function” claims (Blumenthal 2003).

### Use(s) or Purpose(s)

- ▶ (Traditionally used in Herbal Medicine as a) hepatoprotectant/ liver protectant (Bradley 2006; Hoffmann 2003; Blumenthal et al. 2000; Mills and Bone 2000; Ellingwood 1983; Felter and Lloyd 1983; Wren 1907).
- ▶ (Used in Herbal Medicine to) help(s) to support liver function (Velussi et al. 1997; Fehér et al. 1989; Salmi and Sarna 1982; Magliulo et al. 1978).
- ▶ Used in Herbal Medicine to help relieve digestive disturbances/dyspepsia (Blumenthal et al. 2000; Mills 1993).

### Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

### Dose(s)

#### Subpopulation(s)

Adults 18 years and older

#### Quantity(ies)

*Hepatoprotectant/Liver protectant agent; Liver function*

Methods of preparation: Dry, Powder, Non-Standardised ethanolic Extracts (Dry extract, Tincture, Fluid Extract)

3 - 14.5 grams of dried fruit/seed, per day; Not to exceed 4 grams per single dose (Blumenthal et al. 2000; Mills and Bone 2000; Mills 1993).

*Digestive disturbances/dyspepsia*

Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid Extract, Decoction, Infusion)

3 - 14.5 grams of dried fruit/seed, per day; Not to exceed 4 grams per single dose (Blumenthal et al. 2000; Mills and Bone 2000; Mills 1993).



### *All uses*

Methods of preparation: Standardised Extracts (Dry extract, Tincture, Fluid Extract, Decoction, Infusion)

140 - 600 milligrams of silymarin (calculated as silibin/silybin), per day; Not to exceed 200 milligrams per single dose (Williamson 2003; Blumenthal et al. 2000; Mills and Bone 2000; Velussi et al. 1997; Fehér et al. 1989; Salmi and Sarna 1982; Magliulo et al. 1978).

### **Direction(s) for use**

No statement required.

### **Duration(s) of use**

*Hepatoprotectant/Liver protectant agent; Liver function*

Use for at least 3 weeks to see beneficial effects (Flora et al. 1998; Magliulo et al. 1978).

*Digestive disturbances/dyspepsia*

No statement required.

### **Risk information**

#### **Caution(s) and warning(s)**

- ▶ Consult a health care practitioner/health care provider/health care professional/ doctor/ physician if symptoms persist or worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional /doctor/ physician prior to use if you are pregnant (Brinker 2010; Mills et al. 2006).

#### **Contraindication(s)**

No statement required.

#### **Known adverse reaction(s)**

Stop use if hypersensitivity/allergy occurs (Geier et al. 1990; Mironets et al. 1990).



## Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

## Storage conditions

No statement required.

## Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

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