

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 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 on the label.

Date

May 30, 2025

Proper name(s), Common name(s), Source information

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

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

References: Proper name: USDA 2024; Common names: USDA 2024; Gardner and McGuffin 2013; Source information: 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

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).

Notes

- The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Used in Herbal Medicine to help support liver function and relieve digestive disturbances).
- **For multi-ingredient products:**
 - To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Milk thistle is traditionally used in Herbal Medicine as a hepatoprotectant).
 - When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required.

Dose(s)

Subpopulation(s)

Adults 18 years and older



Quantity(ies)

Hepatoprotectant/Liver protectant agent; Liver function

Methods of preparation: Dry, Powdered, Non-Standardized 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, Powdered, Non-Standardized Extracts (Dry extract*, Tincture, Fluid Extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate)

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).

***Note:** Solvents allowed for the method of preparation “Non-Standardized Extracts (Dry extract)” as part of this monograph are ethanol and/or water only.

All uses

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

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)

- **Ask a health care practitioner/health care provider/health care professional/ doctor/ physician if symptoms persist or worsen.**
- **Ask a health care practitioner/health care provider/health care professional /doctor/ physician before 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

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

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.



EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts
Medicinal ingredient in each capsule <i>Silybum marianum</i> (Milk thistle) X:1 extract XX mg Equivalent to YY g dried fruit
Uses <ul style="list-style-type: none"> • Used in Herbal Medicine as a liver protectant. • Used in Herbal Medicine to help relieve digestive disturbances.
Warnings
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame
Ask a health care practitioner before use if you are pregnant.
Stop use if allergy occurs.
Ask a health care practitioner if symptoms persist or worsen.
Directions Adults 18 years and older: • Take X capsule(s), X time(s) per day • Use for at least 3 weeks to see beneficial effects ² .
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

¹This section can be removed from the table if the product contains no allergen or aspartame.

²Hepatoprotectant/Liver protectant agent; Liver function.

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