

NATURAL HEALTH PRODUCT

HAWTHORN

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

July 30, 2021

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>Crataegus laevigata</i>	<ul style="list-style-type: none"> ▶ English hawthorn ▶ Hawthorn ▶ Maytree ▶ Two-style hawthorn ▶ Whitethorn ▶ Woodland hawthorn 	<i>Crataegus laevigata</i>	<ul style="list-style-type: none"> ▶ Fruit ▶ Flower and leaf 	Dried
<i>Crataegus monogyna</i>	<ul style="list-style-type: none"> ▶ Hawthorn ▶ Oneseed hawthorn ▶ One-style hawthorn 	<i>Crataegus monogyna</i>		

References: Proper names: USDA 2019; Common names: Wichtl 2004, McGuffin et al. 2000; Source information: ESCOP 2009, Barnes 2007, Bradley 2006, Belz and Loew 2003, Degenring et al. 2003, ESCOP 2003, Mills and Bone 2000, WHO 1999, Grieve 1971.

Route of administration

Oral (ESCOP 2009; Bradley 2006; Mills and Bone 2000)



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.

Use(s) or Purpose(s)

Fruit

(Traditionally) used in Herbal Medicine to help maintain and/or support cardiovascular health in adults (ESCOP 2009; Bradley 2006; Wichtl 2004; Degenring et al. 2003; ESCOP 2003; Mills and Bone 2000; WHO 1999; Grieve 1971).

Flower and leaf

Used in Herbal Medicine to help maintain and/or support cardiovascular health in adults (Bradley 2006; Wichtl 2004; ESCOP 2003; Mills and Bone 2000; WHO 1999).

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)¹

Fruit

Traditional Herbal Medicine and Herbal Medicine claims (non-traditional)

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

0.6 - 3.5 grams of dried fruit, per day (ESCOP 2009; Bradley 2006; Grieve 1971).



Herbal Medicine claim (non-traditional)

Methods of preparation: Standardized ethanolic extracts (Dry extract)

300 - 750 milligrams of extract, per day, standardized to 0.9 - 10% of Oligomeric proanthocyanidins (OPC) (Godfrey and Saunders 2010; Degenring 2003).

Flower and leaf

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

1.5 - 5 grams of dried flower and leaf, per day (Bradley 2006; ESCOP 2003).

Methods of preparation: Standardized ethanolic extracts (Dry extract)

160 - 900 milligrams of extract, per day, standardized to 18.75% of Oligomeric procyanidins, as epi-catechin, and/or to 2.2% of flavonoids, as hyperoside (Blumenthal et al. 2000; WHO 1999).

Note

¹If both *Crataegus* species are used in a product formulation, the total amount of fruit, flower and leaf or standardized extract should be within the quantity ranges listed on the monograph.

Direction(s) for use

No statement required.

Duration(s) of use

Use for at least two months to see beneficial effects (Mills and Bone 2000).

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 taking cardiac glycosides such as digitalis/digoxin, or blood pressure medication (Brinker 2010; Bradley 2006).

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

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* (NHPR).

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.

References cited

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