Health Canada Santé Canada

NATURAL HEALTH PRODUCT

GINKGO - *GINKGO BILOBA*

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

January 27, 2023

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)
Ginkgo biloba	▸ Baiguo ▸ Ginkgo ▸ Ginkgo biloba ▸ Icho ▸ Maidenhair-tree	*Ginkgo biloba*	Leaf

References: Proper name: USDA 2018; Common names: USDA 2018, McGuffin et al. 2000, WHO 1999, Source information: Birks and Evans 2007.

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.

Use(s) or Purpose(s)

- Helps to enhance cognitive function in adults (Cieza et al. 2003; Santos et al. 2003; Mix and Crews 2002; Stough et al. 2001; Kennedy et al. 2000; Mix and Crews 2000).
- Helps to enhance memory in adults (Santos et al. 2003; Stough et al. 2001; Kennedy et al. 2000; Mix and Crews 2000).
- Helps to support peripheral circulation (Boelsma et al. 2004; Mehlsen et al. 2002; Pittler and Ernst 2000).

The following combined use(s) or purpose(s) is/are also acceptable:

Helps to enhance cognitive function and memory in adults (Cieza et al. 2003; Santos et al. 2003; Mix and Crews 2002; Stough et al. 2001; Kennedy et al. 2000; Mix and Crews 2000).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of Preparation: Standardized Extracts (Dry extract)

80 - 240 milligrams of extract, per day (50:1; quantity crude equivalent 4 – 12 grams of dried leaves), standardized to 22-27% flavonoid glycosides and 5-7% terpene lactones; and providing at least 80 milligrams of extract per single dose (Crew et al. 2005; Cieza et al. 2003; Santos et al. 2003; Mix and Crews 2002; Blumenthal et al. 2000; Kennedy et al. 2000; Pittler and Ernst 2000; WHO 1999).

Direction(s) for use

No statement required.

Duration(s) of use

Products providing 80 mg to less than 120 mg of extract (4 g to less than 6 g dried leaves), per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 8 months (Santos et al. 2003; Le Bars et al. 1997; Grassel 1992).

Products providing 120 mg to 180 mg of extract (6 g to 9 g dried leaves), per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 6 weeks (Elsabagh et al. 2005; Mix and Crews 2002; Mix and Crews 2000).
Products providing more than 180 mg to 240 mg of extract (more than 9 g to 12 g dried leaves), per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4 weeks (Cieza et al. 2003).

Risk information

Caution(s) and warning(s)

- Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding (Blumenthal et al. 2000; WHO 1999).
- Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking medications for diabetes, high blood pressure or seizures (Brinker 2018).

Contraindication(s)

Do not use this product if you are taking health products that affect blood coagulation as this may increase the risk of spontaneous bleeding (Brinker 2018; Bent 2005).

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.
- Ginkgolic acids: Testing must be performed to ensure that the finished product meets the toxicity restrictions for Ginkgolic acids of not more than 5 ppm [USP 43-NF38; Ph.eur. 11th edition 2022 (11.1); Boateng and Yang 2022; Boateng 2022].

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