

NATURAL HEALTH PRODUCT

CAFFEINE

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

March 31, 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 ingredient(s)
<ul style="list-style-type: none"> ▶ 1,3,7-Trimethylxanthine ▶ 3,7-Dihydro-1,3,7-trimethyl-1H-purine-2,6-dione 	Caffeine	<ul style="list-style-type: none"> ▶ Caffeine ▶ Caffeine citrate

References: Proper names: USP 30 2007; Common name: USP 30 2007, IOM 2003; Source information: Ashihara and Suzuki 2004, Zajac et al. 2003, Gennaro 2000.

Route of administration

Oral (Higdon and Frei 2006)

Dosage form(s)

This monograph does not apply to caffeine added to food. Caffeine is regulated as a food additive when it is added to foods, including beverages, chewing gum, and bars. Questions about using caffeine in food can be sent to the Food Directorate (food-aliment@hc-sc.gc.ca).

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 (temporarily) to promote alertness and wakefulness, and to enhance cognitive performance (Christopher et al. 2005; Kamimori et al. 2000; Zwyghuizen-Doorenbos et al. 1990).
- ▶ Helps (temporarily) to support/promote mental sharpness/alertness (Christopher et al. 2005; Kamimori et al. 2000; Zwyghuizen-Doorenbos et al. 1990).
- ▶ Helps (temporarily) to relieve fatigue, to promote endurance, and to enhance motor performance (Philip et al. 2006; Doherty and Smith 2005; Smith et al. 2005).
- ▶ Helps (temporarily) to enhance (physical) energy (Philip et al. 2006; Doherty and Smith 2005; Smith et al. 2005).
- ▶ Helps (temporarily) to reduce tiredness and fatigue (Philip et al. 2006; Doherty and Smith 2005; Smith et al. 2005).
- ▶ Used (temporarily) as a mild diuretic (Shirley et al. 2002; Neuhäuser-Berthold et al. 1997).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Mild diuretic

100 - 200 milligrams caffeine, per single dose; Not to exceed 800 milligrams, per day (Shirley et al. 2002; IOM 2001; Neuhäuser-Berthold et al. 1997).

Other uses

100 - 200 milligrams caffeine, per single dose; Not to exceed 1000 milligrams, per day (Sawynok 1995; FDA 1988; Greden 1974).

Direction(s) for use

Products providing more than 200 mg caffeine, per day (i.e. to be taken in divided doses)

Wait 3 to 4 hours between each dose.

Duration(s) of use

Mild diuretic or products providing more than 400 mg of caffeine, per day

For occasional use only (Higdon and Frei 2006; Juliano and Griffiths 2004; Evans and Griffiths 1999)

Risk information

Caution(s) and warning(s)

All products

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have high blood pressure, glaucoma, and/or overactive bladder syndrome (detrusor instability) (Cornelis and El-Sohemy 2007, Chandrasekaran et al. 2005, Noordzij et al. 2005, Avisar et al. 2002, Arya et al. 2000, Jee et al. 1999, Creighton and Stanton 1990).
- ▶ Avoid taking with health products or foods that contain caffeine and/or increase blood pressure (e.g. medications, coffee, tea, colas, cocoa, guarana, mate, bitter orange extract, synephrine, ocotopamine, ephedra, ephedrine) (Bui et al. 2006; Bouchard et al. 2005; Haller et al. 2005; FDA 2004; Berardi et al. 2002; Vahedi et al. 2000; Zimmerman 1992; FDA 1988).
- ▶ This product is not intended as a substitute for sleep (Berardi et al. 2002, Zimmerman 1992, FDA 1988).

Products providing 200 mg or more caffeine, per day and recommended for endurance, motor performance, physical energy or to be taken prior to workout

Caffeine has been shown to reduce blood flow to the heart muscle during exercise which might lead to cardiovascular complications such as chest pain, and irregular heartbeat even in healthy individuals. If those symptoms occur, stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician (Higgins and Babu 2013).

Products providing more than 300 mg caffeine, per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician if you are of childbearing age, pregnant or breastfeeding (Nawrot et al. 2003).

Contraindication(s)

No statement required.

Known adverse reaction(s)

All products

Stop use if hypersensitivity/allergy occurs (Infante et al. 2003; Hinrichs et al. 2002).

Products providing more than 600 mg caffeine, per day

Caffeine may cause anxiety, rapid heart rate (tachycardia), palpitations, insomnia, restlessness, nervousness, tremor and headache (IOM 2001, Zhang 2001, Sawynok 1995).

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 Database (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

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