Health Canada Santé Canada

NATURAL HEALTH PRODUCT

PLANT STANOL ESTERS

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 21, 2022

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)
Plant stanol esters	Plant stanol esters	▸ *Glycine max* ▸ *Gossypium herbaceum*	Seed
		▸ *Arachis hypogaea* ▸ *Brassica napus* ▸ *Olea europaea* ▸ *Secale cereale* ▸ *Triticum aestivum* ▸ *Zea mays*	Whole plant

References: Proper name: FDA 2018, EC 2002, FDA 2001; Common name: FDA 2018, EC 2002, FDA 2001; Source information: USDA 2019, EC 2002, Kerckhoffs et al. 2002, FDA 2001.

Route of administration

Oral (FDA 2018; de Jong et al. 2008; Hallikainen et al. 2008; Goldberg et al. 2006; Chen et al. 2005; FDA 2001)

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 lower blood total and low density lipoprotein (LDL) cholesterol (FDA 2018; de Jong et al. 2008; Hallikainen et al. 2008; Goldberg et al. 2006; Chen et al. 2005; FDA 2001).
- Helps maintain healthy cholesterol levels (FDA 2018; de Jong et al. 2008; Hallikainen et al. 2008; Goldberg et al. 2006; Chen et al. 2005; FDA 2001).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

1.8 - 5.1 grams of Plant stanol esters per day, including at least 80 % of Combined Sitostanol and Campestanol, per day (FDA 2018; de Jong et al. 2008; Hallikainen et al. 2008; Goldberg et al. 2006; Chen et al. 2005; EC 2002; Kerckhoffs et al. 2002; FDA 2001).

Direction(s) for use

Take with food (FDA 2018; de Jong et al. 2008; Hallikainen et al. 2008; Goldberg et al. 2006; Chen et al. 2005; EC 2002; FDA 2001).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Consult a healthcare practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.

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.

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