



NATURAL HEALTH PRODUCT

PHOSPHATIDYLSERINE

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 1, 2019

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

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

Proper name(s)	Common name(s)	Source ingredient(s)	Source material(s)		
		Common name(s)	Proper name(s)	Part(s)	Preparation(s)
Phosphatidylserine	Phosphatidylserine	N/A	<i>Helianthus annuus</i>	Seed	Isolate
		Phosphatidylserine-enriched soy lecithin	N/A	N/A	N/A
		Phosphatidylserine	N/A	N/A	Synthetic

References: Proper name: NIH 2009; Common name: NIH 2009; Source information: USFDA 2006, USFDA 2003.

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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

Helps support cognitive health and/or brain function (Schreiber et al. 2000; Cenacchi et al.1993; Crook et al. 1992; Engel et al. 1992; Crook et al.1991; Maggioni et al. 1990).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

300 milligrams of Phosphatidylserine, per day (Schreiber et al. 2000; Cenacchi et al.1993; Crook et al. 1992; Engel et al. 1992; Crook et al.1991; Maggioni et al. 1990).

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

No statement required.

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

No statement required.

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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Engel RR, Satzger W, Günther W, Kathmann N, Bove D, Gerke S, Münch U, Hippus. 1992. Double-blind cross-over study of phosphatidylserine vs. placebo in patients with early dementia of the Alzheimer type. *European Neuropsychopharmacology* 2(2):149-155.

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NIH 2009: National Institutes of Health. ChemIDplus advanced [online]. Phosphatidylserine. Bethesda (MD): Specialized Information Services, United States National Library of Medicine, National Institutes of Health, United States Department of Health & Human Services. [Accessed 2019 May 22]. Available from: <http://chem.sis.nlm.nih.gov/chemidplus>

Schreiber S, Kampf-Sherf O, Gorfine M, Kelly D, Oppenheim Y, Lerer B. 2000. An open trial of plant-source derived phosphatidylserine for treatment of age-related cognitive decline. *Israel Journal of Psychiatry & Related Sciences* 37(4):302-307.



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USFDA 2003: United States Food and Drug Administration: Phosphatidylserine and Cognitive Dysfunction and Dementia (Qualified Health Claim: Final Decision Letter) [online]. Silver Spring (MD): United States Department of Health and Human Services, United States Food and Drug Administration. [Accessed 2019 May 22]. Available from: <http://wayback.archive-it.org/7993/20171114183737/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072999.htm>

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