

Phosphatidylserine

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PHOSPHATIDYLSERINE Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 46 KB) 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 Helianthus annuus 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 any age category listed in this monograph for the specified route of administration are listed 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 Cenacchi T, Bertoldin T, Farina C, Fiori MG, Crepaldi G. 1993. Cognitive decline in the elderly: a double-blind, placebo-controlled multicenter study on efficacy of phosphatidylserine administration. *Aging* 5(2):123-133. Crook T, Petrie W, Wells C, Massari DC. 1992. Effects of phosphatidylserine in Alzheimer's disease. *Psychopharmacology Bulletin* 28(1):61-66. Crook TH, Tinklenberg J, Yesavage J, Petrie W, Nunzi MG, Massari DC. 1991. Effects of phosphatidylserine in age-associated memory impairment. *Neurology* 41(5):644-649. 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. Maggioni M, Picotti GB, Bondiolotti GP, Paherai A, Cenacchi T, Nobile P, Brambilla F. 1990. Effects of phosphatidylserine therapy in geriatric patients with depressive disorders. *Acta Psychiatrica Scandinavica* 81(3):265-270. 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. USFDA 2006: United States Food and Drug Administration. Center for Food Safety and Applied Nutrition (CFSAN)/Office of Food Additive Safety: Agency Response Letter GRAS Notice No. GRN 000186 [online]. College Park (MD): Center for Food Safety and Applied Nutrition (CFSAN)/Office of Food Additive Safety, US Food and Drug Administration. [Accessed 2019 May 22]. Available from: <https://wayback.archive-it.org/7993/20171031031859/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154650.htm> 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/ucm_072999.htm References Reviewed Baumeister J, Barthel T, Geiss KR, Weiss M. 2008. Influence of phosphatidylserine on cognitive performance and cortical activity after induced stress. *Nutritional Neuroscience* 11(3):103-110. Jorissen BL, Brouns F, Van Boxtel MP, Riedel WJ. 2002. Safety of soy-derived phosphatidylserine in elderly people. *Nutritional Neuroscience* 5(5):337-343. McDaniel MA, Maier SF, Einstein GO. 2003. "Brain-specific" nutrients: a memory cure? *Nutrition* 19(11-12):957-975. USFDA 2006b: United States Food and Drug Administration. Center for Food Safety and Applied Nutrition (CFSAN)/Office of Food Additive Safety: Agency Response Letter GRAS Notice No. GRN 000197 [online]. College Park (MD): Center for Food Safety and Applied Nutrition (CFSAN)/Office of Food Additive Safety, US Food and Drug Administration. [Accessed 2009 June 10]. Available from: <http://www.fda.gov/v/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm154674.htm> Date Modified 2008-12-19 Top of page Important Notices

MEDICINAL INGREDIENT(S)

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.

DOSAGE FORM(S)

Acceptable dosage forms for any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document.

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.

STORAGE CONDITION(S)

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

Route of Administration Oral

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	Helianthus annuus	Seed	Isola
Phosphatidylserine-enriched soy lecithin	N/A	N/A	N/A		
Phosphatidylserine	N/A	N/A	Synthetic		