



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2016
EMA/HMPC/338889/2016
Committee on Herbal Medicinal Products (HMPC)

List of references supporting the assessment of *Glycine max* (L.) Merr., lecithin

Draft

The European Medicines Agency acknowledges that copies of the underlying works used to produce this monograph were provided for research only with exclusion of any commercial purpose.

Bell JM, Lundberg PK. Effects of a commercial soy lecithin preparation on development of sensorimotor behavior and brain biochemistry in the rat. *Dev Psychobiol* 1985, 18(1): 59-66

Bell JM, Slotkin TA. Perinatal dietary supplementation with a commercial soy lecithin preparation: effects on behavior and brain biochemistry in the developing rat. *Dev Psychobiol* 1985, 18(5): 383-394

Blumenthal M, Goldberg A, Brinckmann J, editors. Herbal Medicine. Expanded Commission E Monographs. The American Botanical Council, Austin Texas 2000, 354-358

Bruneton J. Pharmacognosy, Phytochemistry, Medicinal Plants, 2nd ed, Lavoisier Publishing, France 1999, 147-149

European Medicines Agency (EMA). Public statement on the allergenic potency of herbal medicinal products containing soya or peanut protein. Committee on Herbal Medicinal Products 2006, EMEA/HMPC/138139/2005

European Medicines Agency (EMA). Guideline on clinical investigation of medicinal products in the treatment of lipid disorders (EMA/CHMP/748108/2013)

Gundermann KJ, Kuenker A, Kuntz E, Drożdżik M. Activity of essential phospholipids (EPL) from soybean in liver diseases. *Pharmacol Rep* 2011, 63(3): 643-659

Hänzel R., Keller K., Rimpler H., Schneider G, editors, Hagers Handbuch der Pharmazeutischen Praxis, Drogen E-O. Vol 5. 5th ed. Springer-Verlag, Berlin 1993, 300-311

Honda K, Enoshima T, Oshikata T, Kamiya K, Hamamura M, Yamaguchi N *et al.* Toxicity studies of Asahi Kasei PI, purified phosphatidylinositol from soy lecithin. *J Toxicol Sci* 2009, 34(3): 265-280

Kesaniemi YA, Grundy SM. Effects of dietary polyenylphosphatidylcholine on metabolism of cholesterol and triglycerides in hypertriglyceridemic patients. *Am J Clin Nutr* 1986, 43(1): 98-107



- Lim W. Antiphospholipid syndrome. *Hematology Am Soc Hematol Educ Program* 2013, 2013: 675-680
- Martindale. *The Extra Pharmacopoeia*. 29th ed. The Pharmaceutical Press, London 1989, 1274-1275
- Steinegger E, Hänsel R. *Lehrbuch der Pharmakognosie*. Springer Verlag Berlin-Heidelberg-New York 1972, 361-364
- ter Welle HF, van Gent CM, Dekker W, Willebrands AF. The effect of soya lecithin on serum lipid values in type II hyperlipoproteinemia. *Acta Med Scand* 1974, 195(4): 267-271
- The Review of Natural Products. Monograph: Lecithin. Der Marderosian A, Beutler J editors. Facts and Comparisons, A Wolters Kluwer Company, <http://online.statref.com/>, created July 17, 2007; modified December 18, 2014. Accessed 26/5/2015
- Tuthill JI, Khamashta MA. Management of antiphospholipid syndrome. *J Autoimmun* 2009, 33(2): 92-98
- van Ee J.H. Soy constituents: Modes of action in low-density lipoprotein management. *Nutrition Reviews* 2009, 67(4): 222-234
- Zierenberg O, Grundy SM. Intestinal absorption of polyenephosphatidylcholine in man. *J Lipid Res* 1982, 23: 1136-1142

Excluded non-clinical studies

- Chandrasiri V, Villaume C, Bau HM, Mejean L. Effects of the nature of dietary proteins, lecithin and methionine on rat plasma lipids. *Arch Int Physiol Biochim Biophys* 1991, 99(4): 291-295
- Hunt CE, Duncan LA. Hyperlipoproteinaemia and atherosclerosis in rabbits fed low-level cholesterol and lecithin. *Br J Exp Pathol* 1985, 66: 35-46
- Ishida T, Koba K, Sugano M, Imaizumi K, Watanabe S, Minoshima R. Cholesterol levels and eicosanoid production in rats fed phosphatidylinositol or soybean lecithin. *J Nutr Sci Vitaminol (Tokyo)* 1988, 34(2): 237-244
- Jimenez MA, Scarino ML, Vignolini F, Mengheri E. Evidence that polyunsaturated lecithin induces a reduction in plasma cholesterol level and favorable changes in lipoprotein composition in hypercholesterolemic rats. *J Nutr* 1990, 120: 659-667
- O'Brien BC, Corrigan SM. Influence of dietary soybean and egg lecithins on lipid responses in cholesterol-fed guinea pigs. *Lipids* 1988, 23(7): 647-650
- O'Mullane JE, Hawthorne JN. A comparison of the effects of feeding linoleic acid-rich lecithin or corn oil on cholesterol absorption and metabolism in the rat. *Atherosclerosis* 1982, 45(1): 81-90
- Wilson TA, Meservey CM, Nicolosi RJ. Soy lecithin reduces plasma lipoprotein cholesterol and early atherogenesis in hypercholesterolemic monkeys and hamsters: beyond linoleate. *Atherosclerosis* 1998, 140(1): 147-153
- Wong EK, Nicolosi RJ, Low PA, Herd JA, Hayes K. Lecithin influence on hyperlipemia in rhesus monkeys. *Lipids* 1980, 15: 428-433

Excluded clinical studies

- Brook JG, Linn S, Aviram M. Dietary soya lecithin decreases plasma triglyceride levels and inhibits collagen- and ADP-induced platelet aggregation. *Biochem Med Metab Biol* 1986, 35(1): 31-39
- Childs MT, Bowlin JA, Ogilvie JT, Hazzard WR, Albers JJ. The contrasting effects of a dietary soya lecithin product and corn oil on lipoprotein lipids in normolipidemic and familial hypercholesterolemic subjects. *Atherosclerosis* 1981, 38(1-2): 217-228
- Cobb M, Turkki P, Linscheer W, Raheja K. Lecithin supplementation in healthy volunteers: effect on cholesterol esterification and plasma, and bile lipids. *Nutr Metab* 1980, 24(4): 228-237
- Galli C, Tremoli E, Giani E, Maderna P, Gianfranceschi G, Sirtori CR. Oral polyunsaturated phosphatidylcholine reduces platelet lipid and cholesterol contents in healthy volunteers. *Lipids* 1985, 20(9): 561-566
- Greten H, Raetzer H, Stiehl A, Schettler G. The effect of polyunsaturated phosphatidylcholine on plasma lipids and fecal sterol excretion. *Atherosclerosis* 1980, 36(1): 81-88
- Høie LH, Morgenstern EC, Gruenwald J, Graubaum HJ, Busch R, Lüder W, Zunft HJ. A double-blind placebo-controlled clinical trial compares the cholesterol-lowering effects of two different soy protein preparations in hypercholesterolemic subjects. *Eur J Nutr* 2005, 44(2): 65-71
- Kirsten R, Heintz B, Nelson K, Hesse K, Schneider E, Oremek G, Nemeth N. Polyenyolphosphatidylcholine improves the lipoprotein profile in diabetic patients. *Int J Clin Pharmacol Ther* 1994, 32(2): 53-56
- Kirsten R, Heintz B, Nelson K, Oremek G. Reduction of hyperlipidemia with 3-sn-polyenyolphosphatidylcholine in dialysis patients. *Int J Clin Pharmacol Ther Toxicol* 1989, 27(3): 129-134
- Knuiman JT, Beynen AC, Katan MB. Lecithin intake and serum cholesterol. *Am J Clin Nutr* 1989, 49(2): 266-268
- Mensink RP, Zock PL, Kester AD, Katan MB. Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials. *Am J Clin Nutr* 2003, 77(5): 1146-1155
- Mourad AM, de Carvalho Pincinato E, Mazzola PG, Sabha M, Moriel P. Influence of soy lecithin administration on hypercholesterolemia. *Cholesterol* 2010
- Oosthuizen W, Vorster HH, Vermaak WJ, Smuts CM, Jerling JC, Veldman FJ, Burger HM. Lecithin has no effect on serum lipoprotein, plasma fibrinogen and macro molecular protein complex levels in hyperlipidaemic men in a double-blind controlled study. *Eur J Clin Nutr* 1998, 52(6): 419-424
- Simons LA, Hickie JB, Ruys J. Treatment of hypercholesterolaemia with oral lecithin. *Aust N Z J Med* 1977, 7(3): 262-266
- Sirtori CR, Zucchi-Dentone C, Sirtori M, Gatti E, Descovich GC, Gaddi A, Cattin L, Da Col PG, Senin U, Mannarino E. Cholesterol-lowering and HDL-raising properties of lecithinated soy proteins in type II hyperlipidemic patients. *Ann Nutr Metab* 1985, 29(6): 348-357
- Tompkins RK, Parkin LG. Effects of long-term ingestion of soya phospholipids on serum lipids in humans. *Am J Surg* 1980, 140(3): 360-364
- Wojcicki J., Pawlik A., Samochowiec L., Kaldonska M., Mysiliwiec Z. Clinical evaluation of lecithin as a lipid-lowering agent. *Phytotherapy Research* 1995, 9(8): 597-599