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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Glycine max* (L.) Merr., lecithin

Draft

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BG (bulgarski): Соев лецитин	IT (italiano): lecitina di soia
CS (čeština): sójový lecithin	LT (lietuvių kalba): Sojų lecitinas
DA (dansk): Sojalecithin	LV (latviešu valoda):
DE (Deutsch): Sojabohnen, Phospholipide aus Sojabohnen	MT (Malti): Leċitina tas-sojja
EL (elliniká): Λεκιθίνη από σόγια	NL (Nederlands):
EN (English): soya-bean lecithin	PL (polski): Lecytyna sojowa
ES (español): Lecitina de soja	PT (português): Lecitina de soja
ET (eesti keel): sojaletsitiin	RO (română): soia, lecitină
FI (suomi): soija, lesitiini	SK (slovenčina): sója fazuľová, lecitín
FR (français):	SL (slovenščina): lecitin iz soje
HR (hrvatski): Sojin lecitin	SV (svenska): sojalecitin
HU (magyar): szójalecitin	IS (íslenska):
	NO (norsk): Soyalecitin

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European Union herbal monograph on *Glycine max* (L.) Merr., lecithin

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[1,2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Glycine max* (L.) Merr., lecithin (soya-bean lecithin) i) Herbal substance Not applicable ii) Herbal preparations Soya-bean lecithin (deoiled, enriched phospholipids from soya bean)

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in liquid or solid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for the relief of temporary fatigue and sensation of weakness. The product is a traditional herbal medicinal product for use in the specified indication

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[2] Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State.

Well-established use	Traditional use
	exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* Single dose: 750 - 2700 mg, 2-3 times daily The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance, soya, peanut and to other plants of the Fabaceae (legume) family and to birch pollen. Dietary soya-products are known to cause allergic reactions including severe anaphylaxis in persons with soya allergy. Patients with known allergy to peanut protein carry an enhanced risk for severe reactions to soya preparations.[3]

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. The use in children under 12 years of age has not been established due to lack of adequate

[3] In accordance with the 'Public statement on the allergenic potency of herbal medicinal products containing soya or peanut protein' (EMA/HMPC/138139/2005).

Well-established use	Traditional use
	data.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No fertility data available.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	Soya lecithin has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Well-established use	Traditional use
	Allergic reactions including severe anaphylaxis and angioedema have been reported. The frequency is not known. Skin reactions like pruritus, dermatitis, exanthema and urticaria have been reported. The frequency is not known. Gastrointestinal disorders like stomach discomfort and diarrhoea have been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Adequate tests on reproductive toxicity and genotoxicity have not been performed. Tests on carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation / last revision

12 July 2016