6 May 2026
EMA/HMPC/216490/2025
Committee on Herbal Medicinal Products (HMPC)

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

Draft – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	March 2014 November 2015 April 2016 May/June 2016
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	12 July 2016
Start of public consultation	27 July 2016
End of consultation (deadline for comments)	31 October 2016
Rediscussion in MLWP	November 2016
Adoption by HMPC Monograph (EMA/HMPC/220599/2016) Assessment Report (EMA/HMPC/220598/2016) List of References (EMA/HMPC/ 338889/2016) Overview of Comments received during the public consultation (EMA/HMPC/748525/2016) HMPC Opinion (EMA/HMPC/66450/2017)	31 January 2017
First revision	
Discussion in HMPC	July 2025 September 2025 November 2025 May 2026
Adopted by HMPC for release for consultation	6 May 2026
Start of public consultation	1 June 2026
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	31 August 2026

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Keywords	Committee on Herbal Medicinal Products; HMPC; European Union herbal monographs; herbal medicinal products; traditional herbal medicinal products; traditional use; *Glycine max* (L.) Merr., lecithinum; Lecithinum ex soya; soya-bean lecithin

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

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

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 *Glycine max* (L.) Merr., lecithinum (soya-bean lecithin) i) Herbal substance Not applicable. ii) Herbal preparations Soya-bean lecithin (de-oiled phospholipids from soya bean).

3. Pharmaceutical form

To be specified for the individual finished product.

4. Clinical particulars

4.1. Therapeutic indications

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

[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.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults and elderly* Single dose: 750-1350 mg 2-3 times daily Daily dose: 1500-4050 mg <u>Paediatric population</u> *Adolescents* Single dose: 750 mg 2 times daily Daily dose: 1500 mg The use in children under 12 years of age has not been established. **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.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Severe allergic reactions including anaphylaxis and angioedema have been reported (see section 4.8). Patients should be advised to immediately stop using the product in case of symptoms of allergic reactions.

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

Well-established use	Traditional use
	No interaction studies have been performed.

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-bean lecithin has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Well-established use	Traditional use
	Immune system disorders: anaphylaxis, angioedema. Frequency: not known. Investigations: increased blood pressure. Frequency: not known. Cardiac disorders: palpitations. Frequency: not known. Nervous system disorders: dizziness. Frequency: not known. Skin and subcutaneous tissue disorders: pruritus, dermatitis, exanthema, urticaria. Frequency: not known. Gastrointestinal disorders: diarrhoea, nausea, vomiting. Frequency: not known.

4.9. Overdose

Well-established use	Traditional use
	No information available.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	No information required.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	No information required.

5.3. Preclinical safety data

Well-established use	Traditional use
	Adequate tests on reproductive toxicity and genotoxicity have not been performed. Tests on carcinogenicity have not been performed.

Additional information

Well-established use	Traditional use
	Not applicable.