



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Herbal medicine: summary for the public

Soya-bean lecithin

Glycine max (L.) Merr., lecithinum

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of soya-bean lecithin. The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing soya-bean lecithin.

This summary is not intended to provide practical advice on how to use medicines containing soya-bean lecithin. For practical information about using soya-bean lecithin medicines, patients should read the package leaflet that comes with the medicine or contact their doctor or pharmacist.

What is soya-bean lecithin?

Soya-bean lecithin is the common name for a specific substance obtained from the beans of the plant *Glycine max* (L.) Merr.

Herbal medicines containing soya-bean lecithin are usually available in solid or liquid forms to be taken by mouth.

Soya-bean lecithin may also be found in combination with other herbal substances in some herbal medicines. These combinations are not covered in this summary.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that, on the basis of its long-standing use, soya-bean lecithin can be used for the relief of tiredness and feeling of weakness.

Soya-bean lecithin medicines should only be used in adults and adolescents over the age of 12 years. If the symptoms last longer than 2 weeks or worsen whilst taking the medicine, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take soya-bean lecithin medicines and who can use them can be found in the package leaflet that comes with the medicine.



What evidence supports the use of soya-bean lecithin medicines?

The HMPC conclusions on the use of soya-bean lecithin medicines for tiredness and weakness are based on their 'traditional use'. This means that, although there is insufficient evidence from clinical trials, the effectiveness of these herbal medicines is plausible and there is evidence that they have been used safely in this way for at least 30 years (including at least 15 years within the EU). Moreover, the intended use does not require medical supervision.

The HMPC noted the lack of relevant laboratory and clinical studies with soya-bean lecithin and its conclusions are therefore based on the long-standing use of this herbal substance.

For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with soya-bean lecithin medicines?

Side effects reported with soya-bean lecithin medicines include allergic reactions such as angioedema (swelling under the skin), and skin reactions such as itching, dermatitis (inflammation of the skin) and exanthema (widespread rash). Stomach ache and diarrhoea may also occur. The frequency of these side effects is not known.

Soya-bean lecithin medicines must not be taken by people who are hypersensitive (allergic) to soya-bean lecithin, soya, peanut, to other plants of the legume family (which includes beans, lentils and peas) or to birch pollen.

Further information on the risks associated with these soya-bean lecithin medicines, including the appropriate precautions for their safe use, can be found in the monograph under the tab 'All documents' on the Agency's website: [ema.europa.eu/Find medicine/Herbal medicines for human use](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use).

How are soya-bean lecithin medicines approved in the EU?

Any applications for the licensing of medicines containing soya-bean lecithin have to be submitted to the national authorities responsible for medicinal products, which will assess the application for the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of soya-bean lecithin medicines in EU Member States should be obtained from the relevant national authorities.

Other information about soya-bean lecithin medicines

Further information on the HMPC assessment of soya-bean lecithin medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: [ema.europa.eu/Find medicine/Herbal medicines for human use](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use). For more information about treatment with soya-bean lecithin medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.