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Herbal medicine: summary for the public

Soya-bean oil, refined

Glycine max (L.) Merr., oleum raffinatum

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

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

What is soya-bean oil?

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

Herbal medicines containing soya-bean oil are usually available in liquid forms as bath additives.

Soya-bean oil 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 oil can be used for relief of dry skin associated with mild recurrent eczema (an itchy, red rash).

Soya-bean oil medicines can be used in people of all ages. If symptoms last or worsen while taking the medicine, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to use soya-bean oil 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 oil medicines?

The HMPC conclusions on the use of these soya-bean oil medicines for dry skin 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 laboratory and clinical studies with soya-bean oil 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 oil medicines?

Side effects reported with soya-bean oil medicines include skin rashes and allergic reactions but their frequency is not known. Accidental contact of soya-bean oil medicines with the eyes may cause keratitis (inflammation of the cornea, the transparent layer in front of the eye).

Soya-bean oil medicines must not be taken by people who are hypersensitive (allergic) to soya-bean oil, soya, peanut, or to other plants of the legume family (which includes beans, lentils and peas) or to birch pollen. Baths must not be taken in case of open wounds, large skin injuries, rapidly developing skin diseases, high fever, severe infections, and severe problems with the heart and circulation.

Further information on the risks associated with these soya-bean oil 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.

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

Any applications for the licensing of medicines containing soya-bean oil 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 oil medicines in EU Member States should be obtained from the relevant national authorities.

Other information about soya-bean oil medicines

Further information on the HMPC assessment of soya-bean oil 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. For more information about treatment with soya-bean oil medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.