



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Evening primrose oil

Oenothera biennis L. or *Oenothera lamarckiana* L., oleum

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

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

What is evening primrose oil?

Evening primrose oil is the common name for the fatty oil obtained from the seeds of the plant *Oenothera biennis* L. or *Oenothera lamarckiana* L.

The HMPC conclusions only cover evening primrose oil preparations that are obtained by using a solvent or by pressing the seeds to extract the oil.

Herbal medicines containing these evening primrose oil preparations are usually available in solid forms to be taken by mouth.

Evening primrose oil preparations 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, this evening primrose oil preparation can be used for relief of itching in short-term and long-term dry skin conditions.

Evening primrose oil medicines should only be used in adults and adolescents over the age of 12 years. If symptoms while taking the medicine last longer than 8 weeks, a doctor or healthcare practitioner should be consulted. Detailed instructions on how to take evening primrose 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 evening primrose oil medicines?

The HMPC conclusions on the use of these evening primrose oil medicines for itching in dry skin conditions 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.

In its assessment, the HMPC also considered studies involving patients with dermatitis (skin inflammation). Although a possible effect in improving symptoms of dermatitis was observed, the quality of the evidence was very low to moderate and the number of patients in individual studies was low. Therefore, the HMPC conclusions on the use of these evening primrose oil medicines are based on their long-standing use.

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

What are the risks associated with evening primrose oil medicines?

Side effects with evening primrose oil medicines include effects on the stomach and gut such as indigestion, nausea and softening of stools, increased temperature, hypersensitivity (allergic) reactions such as exanthema (skin rash), and headache. The frequency is not known.

Further information on the risks associated with these evening primrose 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](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use).

How are evening primrose oil medicines approved in the EU?

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

Other information about evening primrose oil medicines

Further information on the HMPC assessment of evening primrose 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](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use). For more information about treatment with evening primrose oil medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.