

12 July 2013 EMA/HMPC/530968/2012 Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

Lavender oil

Lavandula angustifolia Mill., aetheroleum

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

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

What is lavender oil?

Lavender oil is the common name for the essential oil of the plant *Lavandula angustifolia* Mill. The plant is cultivated or gathered to obtain the oil for medicinal use.

Lavender oil is obtained by a current of steam through the flowering tops of the plant.

Herbal medicines containing lavender oil are usually available in liquid forms to be taken by mouth or as a bath additive.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that, on the basis of its long-standing use, lavender oil can be used for the relief of mild symptoms of mental stress and exhaustion, and to aid sleep.

Lavender oil medicines should only be used in adults and children over the age of 12 years. Detailed instruction on how to take lavender oil medicines and who can use them can be found in the package leaflet that comes with the medicine.

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What evidence supports the use of lavender oil medicines?

The HMPC conclusions on the use of medicines containing lavender oil 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 with lavender oil in patients with different conditions, including anxiety and sleeping disorders. Although lavender oil showed a possible effect on anxiety, stress and insomnia, the number of patients per study was too low to establish an effect. Therefore, the HMPC conclusions on the use of lavender oil medicines are based on their long-standing use.

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

What are the risks associated with lavender oil medicines?

At the time of the HMPC assessment, there were no major concerns over the safety of lavender oil. Only few and mild side effects had been reported in studies with lavender oil, including very rare cases of allergic reactions.

Patients with open wounds, skin problems, high fever, severe infections and severe heart and circulation problems should not have full baths with lavender oil.

Further information on the risks associated with lavender 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: <u>ema.europa.eu/Find medicine/Herbal medicines for human use</u>.

How are lavender oil medicines approved in the EU?

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

Other information about lavender oil medicines

Further information on the HMPC assessment of lavender oil, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: <u>ema.europa.eu/Find</u> <u>medicine/Herbal medicines for human use</u>. For more information about treatment with lavender oil, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.