



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 March 2017
EMA/94696/2017

Herbal medicine: summary for the public

Olive leaf

Olea europaea L., folium

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

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

What is olive leaf?

Olive leaf is the common name for the leaf of the plant *Olea europaea* L.

The HMPC conclusions only cover fresh or dried olive leaves and olive leaf preparations obtained by drying and comminuting (reducing into tiny pieces) or powdering the leaves.

Herbal medicines containing these olive leaf preparations are usually available as herbal tea to be drunk and in solid forms to be taken by mouth.

Olive leaf 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, olive leaf and olive leaf preparations can be used to promote water elimination through the kidneys in mild cases of water retention, after serious conditions have been excluded by a doctor.

Olive leaf medicines should only be used in adults. If symptoms last longer than one week or worsen while taking the medicine, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take olive leaf medicines and who can use them can be found in the package leaflet that comes with the medicine.



What evidence supports the use of olive leaf medicines?

The HMPC conclusions on the use of these olive leaf medicines for water elimination 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).

In its assessment, the HMPC also considered laboratory and clinical studies in which olive leaf medicines led to increases in the daily volume of urine. However, since the data are limited the HMPC conclusions on the use of these olive leaf 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 olive leaf medicines?

At the time of the HMPC assessment, no side effects had been reported with these medicines.

Olive leaf medicines must not be taken by patients with conditions where reduced fluid intake is recommended such as severe heart or kidney disease.

Further information on the risks associated with these olive leaf 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 olive leaf medicines approved in the EU?

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

Other information about olive leaf medicines

Further information on the HMPC assessment of olive leaf 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 olive leaf medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.