

13 August 2013 EMA/HMPC/432131/2013 Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

Walnut leaf Juglans regia L., folium

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

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

What is walnut leaf?

Walnut leaf is the common name for the whole leaf of the tree *Juglans regia* L. The leaf is gathered from wild or cultivated trees.

Walnut leaf preparations are obtained by comminuting (reducing into tiny pieces) the dried leaves.

Herbal medicines containing walnut leaf are usually available as comminuted herbal material to be boiled in water to make a 'decoction' which is applied to the skin.

Walnut leaf can 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, walnut leaf can be used for the relief of minor inflammatory conditions of the skin and to reduce excessive sweating of the hands and feet.

Walnut leaf preparations should only be used in adults, and should not be used for longer than one week. If symptoms persist, a doctor should be consulted. Detailed instruction on how to use walnut leaf 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 walnut leaf medicines?

The HMPC conclusions on the use of walnut leaf medicines for minor inflammatory skin conditions and excessive sweating 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 took into account the well documented and very longstanding use of walnut leaf for these indications. The HMPC also noted studies in laboratory tests, which showed that walnut leaf has antimicrobial effects.

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

What are the risks associated with walnut leaf medicines?

At the time of the HMPC assessment, no side effects had been reported with these medicines. In its assessment the HMPC considered the potential effects of juglone (a toxic component of walnut tree) but noted that it is only present in traces (very small amounts) in dry walnut leaf and therefore does not pose a risk to human health.

Walnut leaf medicines must not be applied on open wounds and large skin injuries.

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

How are walnut leaf medicines approved in the EU?

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

Other information about walnut leaf medicines

Further information on the HMPC assessment of walnut leaf medicines, 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 medicine/Herbal medicines for human use</u>. For more information about treatment with walnut leaf medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.