

12 July 2013 EMA/HMPC/300235/2013 Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

Eucalyptus leaf

Eucalyptus globulus Labill., folium

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

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

What is eucalyptus leaf?

Eucalyptus leaf is the common name for the whole or cut leaf of the tree Eucalyptus globulus Labill.

Preparations from dried eucalyptus leaf are obtained by comminuting (reducing into tiny pieces) the dried leaves of older branches of the tree, or by using them to produce a tincture (an alcoholic extract of the plant material).

Herbal medicines containing eucalyptus leaf are usually available as comminuted herbal material for the preparation of a herbal tea to be drunk, an infusion to be inhaled or a liquid to be taken by mouth.

Eucalyptus 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, eucalyptus leaf can be used for the relief of cough associated with a cold.

Comminuted preparations of eucalyptus leaf should only be used in adults and children over the age of 12 years, while tincture preparations should only be used in adults due to high content of ethanol (pure alcohol). If symptoms persist for longer than a week, a doctor should be consulted. Detailed



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instruction on how to take eucalyptus 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 eucalyptus leaf medicines?

The HMPC conclusions on the use of eucalyptus leaf medicines for the relief of cough associated with a cold are based on their 'traditional use' in this condition. 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 considered the results of laboratory tests as well as studies in patients looking in particular at the effects of a component of eucalyptus leaf, called 1,8 cineole (also known as eucalyptol). The studies indicated that 1,8 cineole might have an effect in diseases of the airways. For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with eucalyptus leaf medicines?

At the time of the HMPC assessment, no side effects had been reported with these medicines when used in the way described above.

The HMPC recommended that eucalyptus leaf medicines should not be used in children under 30 months of age because of the risk of laryngospasm (contraction of the vocal cords).

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

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

Other information about eucalyptus leaf medicines

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