



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 November 2016  
EMA/HMPC/288003/2014

## Herbal medicine: summary for the public

---

### Eucalyptus oil

*Eucalyptus globulus* Labill., *Eucalyptus polybractea* R.T. Baker and/or  
*Eucalyptus smithii* R.T. Baker, aetheroleum

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

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

#### **What is eucalyptus oil?**

Eucalyptus oil is the common name for the essential oil from the fresh leaves or terminal branches of plants of different *Eucalyptus* species rich in 1,8-cineole (mainly *Eucalyptus globulus* Labill., *Eucalyptus polybractea* R.T. Baker and/or *Eucalyptus smithii* R.T. Baker).

Eucalyptus oil is obtained by passing a current of steam through the fresh leaves or terminal branches. After cooling, the essential oil separates from the water and can be collected.

Herbal medicines containing this eucalyptus oil preparation are usually available in solid or liquid forms to be taken by mouth, in liquid forms to be inhaled or used as bath additives and in liquid or semi-solid forms to be applied to the skin.

Eucalyptus 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, eucalyptus oil can be used for relief of cough associated with the common cold and symptoms of localised muscle pain.



Eucalyptus oil medicines taken by mouth should only be used in adults and adolescents from 12 years of age, whereas eucalyptus oil medicines taken by inhalation, applied to the skin or used as a bath additive can be used from 4 years of age. If cough symptoms last longer than 1 week during the use of the medicine, a doctor or a qualified healthcare practitioner should be consulted. If muscle pain lasts longer than 1 week during the use of the medicine as bath additive, or longer than 2 weeks when the medicine is applied to the skin, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take eucalyptus 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 eucalyptus oil medicines?**

The HMPC conclusions on the use of these eucalyptus oil medicines for cough associated with cold and localised muscle pain 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 clinical studies in patients with bronchitis (inflammation of the airways in the lung) and asthma. Although some improvement in symptoms was observed, firm conclusions could not be drawn as these studies did not use eucalyptus oil but 1,8-cineole which is the main constituent of eucalyptus oil. Therefore, the HMPC conclusions on the use of these eucalyptus oil medicines in these conditions 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 eucalyptus oil medicines?**

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

Eucalyptus oil medicines must not be given to children with a history of seizures (fits), with or without fever. They must also not be given to children under 30 months of age because there is a risk of spasm of the larynx (voice box). In addition, hot baths with eucalyptus oil must not be taken by patients with large skin injuries and open wounds, acute skin disease, high fever, severe infections, severe problems with blood circulation and heart failure.

Further information on the risks associated with these eucalyptus 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 eucalyptus oil medicines approved in the EU?**

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

### **Other information about eucalyptus oil medicines**

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