



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Herbal medicine: summary for the public

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### Tea tree oil

*Melaleuca alternifolia* (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and/or other species of *Melaleuca*, aetheroleum

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

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

#### **What is tea tree oil?**

Tea tree oil is the common name for the essential oil from the leaves and terminal branches of the trees *Melaleuca alternifolia* Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and other species of *Melaleuca*.

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

Herbal medicines containing tea tree oil preparations are usually available in liquid or semi-solid forms to be applied to the skin and in liquid forms to be applied to the lining of the mouth.

Tea tree 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, these tea tree oil preparations can be used for the treatment of small superficial wounds, insect bites and small boils (furuncles and mild acne), for the relief of itching and irritation in mild athlete's foot, and for the treatment of minor inflammation of the lining of the mouth.



Tea tree oil medicines should only be used in adults and adolescents over the age of 12 years. They should not be taken for longer than 1 month when treating small boils or itching and irritation in mild athlete's foot. If symptoms continue or worsen during the use of the medicine a doctor or a qualified healthcare practitioner should be consulted.

A doctor or a qualified healthcare practitioner should be consulted if symptoms last longer than 5 days when treating mouth inflammation, or longer than 1 week when treating small superficial wounds and insect bites.

Detailed instructions on how to take tea tree 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 tea tree oil medicines?**

The HMPC conclusions on the use of these tea tree oil medicines for wounds, insect bites, small boils, athlete's foot and mouth inflammation 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 involving patients with acne, athlete's foot, superficial wounds and diseases of the mouth. Although tea tree oil was shown to be antiseptic and positive effects were observed, there were shortcomings in the studies such as small numbers of patients and study design. Therefore, the HMPC conclusions on the use of these tea tree oil 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 tea tree oil medicines?**

Side effects reported with tea tree oil medicines include skin reactions such as pain, mild itching, burning sensation, irritation, stinging, redness and swelling, and other allergic reactions. Their frequency is unknown.

Burn-like skin reactions have been reported rarely (in between 1 and 10 patients in 10,000).

Further information on the risks associated with these tea tree 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_medicine/Herbal_medicines_for_human_use).

### **How are tea tree oil medicines approved in the EU?**

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

### **Other information about tea tree oil medicines**

Further information on the HMPC assessment of tea tree 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_medicine/Herbal_medicines_for_human_use). For more information about

treatment with tea tree oil medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.