



12 July 2013  
EMA/HMPC/310761/2013  
Committee on Herbal Medicinal Products (HMPC)

## Herbal medicine: summary for the public

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### Melissa leaf

*Melissa officinalis* L., folium

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

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

#### **What is melissa leaf?**

Melissa leaf is the common name for the leaf of the plant *Melissa officinalis* L. The plant is cultivated or gathered to obtain the leaf for medicinal use.

Melissa leaf preparations are obtained by drying and powdering or comminuting (reducing into tiny pieces) the leaf. This may be used to prepare extracts or tinctures (an alcoholic extract of the plant material).

Herbal medicines containing melissa leaf are usually available as a herbal tea to be drunk, and in solid and liquid forms to be taken by mouth.

Melissa 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, melissa leaf can be used for the relief of mild symptoms of stress and to aid sleep. It can also be used to treat the symptoms of mild digestive disorders including bloating and flatulence (wind).

Melissa leaf should only be used in adults and children over the age of 12 years. A doctor should be consulted if the symptoms persist following 2 weeks of treatment. Detailed instructions on how to take



melissa 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 melissa leaf medicines?**

The HMPC conclusions on the use of melissa leaf medicines for mild symptoms of stress, sleep aid and mild digestive disorders are based on their 'traditional use' in these conditions. 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 these ways for at least 30 years (including at least 15 years within the EU). Moreover, the intended uses do not require medical supervision.

In its assessment, the HMPC took into account the well documented use of Melissa leaf for these indications. The HMPC also considered published clinical studies, including a small study that examined the effects of melissa leaf preparations on symptoms of mild to moderate anxiety and sleep disturbance. Although a possible improvement in symptoms was observed, shortcomings in the design of the study prevented any firm conclusions being drawn. Therefore, the HMPC conclusions on the use of melissa 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 melissa leaf medicines?**

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

Further information on the risks associated with melissa 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](http://ema.europa.eu/Find_medicine/Herbal_medicines_for_human_use).

### **How are melissa leaf medicines approved in the EU?**

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

### **Other information about melissa leaf medicines**

Further information on the HMPC assessment of melissa 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](http://ema.europa.eu/Find_medicine/Herbal_medicines_for_human_use). For more information about treatment with melissa leaf medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.