



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Salvia officinalis* L., aetheroleum

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2009 July 2009 September 2009 November 2009
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	12 November 2009
End of consultation (deadline for comments)	15 May 2010
Rediscussion in MLWP	July 2010
Adoption HMPC	15 July 2010
Keywords	Herbal medicinal products; HMPC; Community herbal monographs; Public statement; <i>Salvia officinalis</i> L.; <i>Salviae officinalis</i> aetheroleum; sage essential oil; sage oil

¹ The presence of thujone in sage leaf preparations mentioned in the monograph has been increased to a daily exposure of 6.0 mg/person for a maximum duration of 2 weeks.



Public statement on *Salvia officinalis* L., aetheroleum

Problem statement

The HMPC has completed the revision of the Community herbal monograph for *Salvia officinalis* L., folium. The HMPC concurrently assessed the toxicological and safety aspects of sage essential oil (=sage oil) and its conclusions can be found in the assessment report on *Salvia officinalis* L., folium. Sage oil is characterised by high levels of thujone. Consumption of the sage oil in single ingredient products involves a high risk of exceeding this maximum recommended daily intake of thujone. Thujone is toxic and may cause seizures at high doses as shown in animal studies and indicated from case reports. The presence of thujone in sage leaf preparations mentioned in the monograph is restricted to a daily exposure of 6.0 mg/person for a maximum duration of 2 weeks.

Conclusions

Under the regulatory framework applicable to traditional herbal medicinal products laid down in Chapter 2a of Directive 2001/83/EC as amended and in particular Article 16a(1)(a) on their use in minor indications that do not require supervision of a medical practitioner, the findings from the assessment imply that the benefit-risk analysis of sage oil is negative. The extent and the quality of the available scientific data have not been sufficient to come to a positive benefit-risk assessment taken into account the expected benefit from the herbal medicinal products. As no data were retrieved for more serious conditions that could alter the benefit/risk assessment, the HMPC has therefore concluded that the benefits of sage oil do not outweigh its risks.

If new information on clinical safety and efficacy of sage oil as a single ingredient were to be made available, such documentation may be re-assessed by the HMPC. The currently available clinical and toxicological data on sage oil can not be considered adequate to fulfil the criteria required for developing a Community herbal monograph.

To read more about the toxicological aspects of thujone and sage oil, links are provided to access the assessment report on sage leaf (*Salvia officinalis* L., folium) and the Public statement on the use of herbal medicinal products containing thujone.

Links:

Assessment report on sage leaf (*Salvia officinalis* L., folium):

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000069.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d

Public statement on the use of herbal medicinal products containing thujone:

<EMA/HMPC/732886/2010 Rev.1>