



EMA/HMPC/11545/2009

This document was valid from 14 January 2009 until January 2017. It is now superseded by a new version adopted by the HMPC on 31 January 2017 and published on the EMA website.

SALIX [VARIOUS SPECIES INCLUDING *S. PURPUREA* L., *S. DAPHNOIDES* VILL.,
S. FRAGILIS L.], CORTEX

Opinion

1. The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC, as amended, and as set out in the appended assessment report, establishes, by a majority of 27 out of 30 votes a Community herbal monograph on *Salix* [various species including *S. purpurea* L., *S. daphnoides* Vill., *S. fragilis* L.], cortex which is set out in Annex I.

The divergent positions are appended to this opinion.

The Norwegian HMPC member agrees with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States, to Iceland and Norway, together with its Annex I and appendices.

The Community herbal monograph and assessment report will be published on the EMA website.

London, 15 January 2009


On behalf of the HMPC
Dr Konstantin Keller, Chair

ANNEX I: COMMUNITY HERBAL MONOGRAPH (EMEA/HMPC/295338/2007)

APPENDIX I: ASSESSMENT REPORT (EMEA/HMPC/295337/2007)

APPENDIX II: DIVERGENT POSITIONS

Three members of the HMPC did not agree with the HMPC's opinion based on the considerations reported below:

1. We do not support the well-established use indication for *Salix* cortex for the short-term treatment of low back pain.

In our view the data provided to support this indication do not fulfil the requirements for well-established use and recognised efficacy in accordance with Annex 1 of 2001/83/EC, as amended. Specifically, the clinical data presented for this indication are insufficient to support the proposed well-established use indication. The contraindications should include haemophilia, haemorrhagic disease, history of bleeding disorders, history of peptic ulceration, gout or history of gout. The interactions section should cover known interactions with aspirin.

2. We do not support the traditional use of *Salix* cortex for the relief of fever associated with common cold with a duration up to 3 days. The contraindications should include haemophilia, haemorrhagic disease, history of bleeding disorders, history of peptic ulceration, gout or history of gout. The interactions section should cover known interactions with aspirin. The traditional herbal preparations should be quantified with respect to salicin derivatives to support the plausibility of the traditional uses.

15 January 2009