



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/66094/2017
EMA/HMPC/M/H/0196
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Salix* [various species including *S. purpurea* L., *S. daphnoides* Vill., *S. fragilis* L.], cortex

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC, and as set out in the appended assessment report, establishes, by a majority of 21 out of 28 votes a European Union 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 European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted 14 January 2009.

London, 31 January 2017



Annex I: European Union herbal monograph (EMA/HMPC/80630/2016)

Appendix I: Assessment report (EMA/HMPC/80628/2016)

Appendix II: Divergent positions

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

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.

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.

Rachel Cox, HMPC member from Ireland

London, 31 January 2017

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

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. 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.

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.

Linda Anderson, HMPC member from UK

London, 31 January 2017

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

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 evidence in supporting its effectiveness are inconclusive according to the existing scientific literature. We consider that the evidence does not support the position of *Salix* as having well-established use and recognised efficacy in according with the Annex I of 2001/83/EC, as amended.

The interactions section should cover known interactions with aspirin.

Anna Maria Serrilli, HMPC member from Italy

London, 31 January 2017

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

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. Specifically, the clinical data presented for this indication are insufficient to support the proposed well-established use indication.

Emiel van Galen, HMPC member from The Netherlands

London, 31 January 2017

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

In the assessment report the content of *Salicis cortex* and its preparations was well presented, and salicylates does not look to be present in cortex nor in its preparations. To the main components may belong for example salicin or tremulacin, but salicylates are absent in *Salicis cortex* preparations. This is the reason that contraindication to salicylates or even to other NSAIDs (e.g. history of angioedema, bronchial spasm, or chronic urticaria in response to salicylates or to other NSAIDs) are not justified. The cases of asthma due to sensitivity to salicylates could be rather a justification for precaution. For the same reason of lack of evidence on the risk of Reye's syndrom in children and adolescents under 18 years of age, using any of *Salix cortex* preparations, it is difficult to regard this contraindication as documented.

Wojciech Dymowski, HMPC member from Poland

London, 31 January 2017

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

In my 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 history of bleeding disorders, history of peptic ulceration, gout or history of gout. The interactions section should contain potential interactions based on the drug interactions known for aspirin.

I 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 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 sustain the plausibility of the traditional uses.

Gioacchino Calapai, Co-opted member of the HMPC
London, 31 January 2017

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

I express my divergent opinion because I do not support the well-established use indication for *Salix cortex* for the short-term treatment of low back pain.

In my 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.

Silvia Giroto, Co-opted member of the HMPC
London, 31 January 2017