



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/HMPC/338763/2017  
EMA/HMPC/M/H/0207  
Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a European Union herbal monograph on *Vitis vinifera* L., folium

### 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 18 out of 24 votes a European Union herbal monograph on *Vitis vinifera* L., folium which is set out in Annex I.

The divergent positions are appended to this opinion.

The Norwegian HMPC member was not present.

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 on 15 July 2010.

London, 30 May 2017



# Annex I: European Union herbal monograph (EMA/HMPC/464684/2016)

## Appendix I: Assessment report (EMA/HMPC/464682/2016)

## Appendix II : Divergent positions

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

Italy does not agree with the HMPC's opinion on Community herbal monograph on Well-established use for *Vitis viniferae* L., folium for the following reasons:

No new clinical studies have been mentioned in the assessment report in addition to those already available at the time of the establishment of the WEU monograph for which Italy expressed a divergent opinion; therefore, it is confirmed that the clinical evidence does not support the position of *Vitis viniferae* L., folium as having a well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

Results of the studies presented as evidence for indication of treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves are contradictory and there is significant inconsistency between trials in terms of subjects, experimental design and procedures and methodological quality.

The evidence in support of this indication and the proposed posology is considered inadequate.

Alessandro Assisi, HMPC Member from Italy

London, 30 May 2017

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

The Finnish representative expressed a divergent opinion on the Monograph and List Entry on *Vitis viniferae* folium as the scientific evidence on the efficacy of the products for the indication proposed for the well-established use side of the monograph is considered insufficient for granting marketing authorization.

Eeva Sofia Leinonen, HMPC Member from Finland

London, 30 May 2017

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

The evidence does not support the position of *Vitis vinifera* folium as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

Results of the studies presented as evidence for the indication of *treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves* are contradictory and there is significant inconsistency between trials in terms of subject, experimental design and procedures and methodological quality.

The evidence in support of this indication and the proposed posology is considered inadequate.

Emiel van Galen, HMPC Member from The Netherlands

London, 30 May 2017

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

I do not support the proposed Union for *Vitis viniferae* folium.

The evidence does not support the position of *Vitis viniferae* folium as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

Results of the studies presented as evidence for the indication of *treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves* are contradictory and there is significant inconsistency between trials in terms of subjects, experimental design and procedures and methodological quality.

The evidence in support of this indication and the proposed posology is considered inadequate.

Linda Anderson, HMPC Member from United Kingdom

London, 30 May 2017



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

I do not support the proposed Union for *Vitis viniferae* folium.

The evidence does not support the position of *Vitis viniferae* folium as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

Results of the studies presented as evidence for the indication of *treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves* are contradictory and there is significant inconsistency between trials in terms of subjects, experimental design and procedures and methodological quality.

The evidence in support of this indication and the proposed posology is considered inadequate.

Una Mockler, HMPC Member from Ireland

London, 30 May 2017

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

The efficacy of the *Vitis vinifera* preparation in Assessment report for the monograph is based on only one publication (from 2000) and the results were not further confirmed in 2003 by other study. Moreover the publication was not available before meeting so I was not sure whether the criteria for well designed clinical study and for WEU, described in Annex 1 for Directive 2001/83/UE, were fulfilled.

Wojciech Dymowski, HMPC Member from Poland

London, 30 May 2017