



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/HMPC/258019/2011  
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Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a Community herbal monograph on *Hedera helix* L., folium

**This document was valid from 31 March 2011 until 24 November 2015.  
It is now superseded by a [new version](#) adopted by the HMPC on  
24 November 2015 and published on the EMA website.**

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 22 out of 28 votes a Community herbal monograph on *Hedera helix* L., folium which is set out in Annex I.

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 European Medicines Agency website.

London, 31 March 2011

On behalf of the HMPC  
Dr Werner Knöss, Chair



**Annex I: Community herbal monograph  
(EMA/HMPC/289430/2009)**

Superseded

**Appendix I: Assessment report (EMA/HMPC/289432/2009)**

Superseded

## Appendix II: Divergent positions

Superseded

Five members of the HMPC did not agree with the HMPC's opinion on *Hedera helix* L., folium for the following reasons:

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

The studies presented as evidence have not been conducted on patients with the proposed indication as an expectorant in productive cough. The studies have been conducted in patients with more serious conditions including bronchitis, COPD and bronchial asthma. Furthermore, the treatment times stated in the studies are generally longer than that proposed in the monograph. The evidence in support of this indication and the proposed posology is considered inadequate. The data to support use in children below 12 years of age is not sufficient to demonstrate safe use.

31 March 2011

Superseded

One member of the HMPC did not agree with the HMPC's opinion on *Hedera helix* L., folium for the following reasons:

Clinical experience with using *Hederae heliis folium* extracts in children, in the age under 5 years is too weak to support well established use of these extracts. In our view, for the safe use of the extracts in this age group of patients, have to be necessary medical consultation.

I share opinions of my colleagues that clinical studies assessed for mentioned Monograph, were performed on large groups of patients, even with more serious clinical conditions, including bronchitis, COPD and studies were longer than proposed in the Monograph. These clinical situations were different that use without medical consultation.

31 March 2011

Superseded