



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/74516/2016
EMA/HMPC/M/H/182
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Ricinus communis* L., oleum

Opinion

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 24 out of 27 votes a European Union herbal monograph on *Ricinus communis* L., oleum 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 European Union herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 2 February 2016



Annex I: European Union herbal monograph (EMA/HMPC/572974/2014)

Appendix I: Assessment report (EMA/HMPC/572973/2014)

Appendix I: Assessment report (EMA/HMPC/150846/2015)

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

The evidence does not support the position of *Ricinus communis* L., oleum as having well-established medicinal use and recognised efficacy as a laxative for short term use in cases of occasional constipation as required by Article 10a of Directive 2001/83/EC. The data are insufficient to support a well-established use indication in accordance with Annex 1 of 2001/83/EC, as amended.

The efficacy of *Ricinus communis* L., oleum has not been sufficiently and consistently proven.

Una Mockler, HMPC member from the Ireland

London 2 February 2016

Two members of the HMPC mentioned below did not agree with the HMPC's opinion for the following reasons:

The evidence does not support the position of *Ricinus communis* L., oleum as having well-established medicinal use and recognised efficacy as a laxative for short term use in cases of occasional constipation as required by Article 10a of Directive 2001/83/EC. The data are insufficient to support a well-established use indication in accordance with Annex 1 of 2001/83/EC, as amended. The efficacy of *Ricinus communis* L., oleum has not been sufficiently and consistently proven.

In addition, the use of *Ricinus communis* L., oleum as a laxative is considered outmoded and obsolete in current clinical practice. Even at therapeutic doses, castor oil can cause excessive irritation of the colon and violent purgation. Safer alternative stimulant laxatives are available and preferred in this indication.

Emiel van Galen, HMPC member from the Netherlands

Linda Anderson, HMPC member from the United Kingdom

London 2 February 2016