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Committee on Herbal Medicinal Products (HMPC)

## Public statement on *Viscum album* L., herba

Draft

Discussion in Working Party on Community Monographs and Community List (MLWP)	May 2009 September 2009 November 2009 September 2010 January 2011 March 2011 May 2011
Adoption by HMPC for release for consultation	September 2011
End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> . The completed comments form should be sent to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	15 February 2012
Rediscussion in MLWP	
Adoption by HMPC	

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# Public statement on *Viscum album* L., herba

## PROBLEM STATEMENT

The HMPC has discussed the Community herbal monograph for *Viscum album* L., herba. The HMPC concurrently assessed the therapeutic aspects of mistletoe. The assessment report is dealing with the following aspects:

- Description of the herbal substance
- Preparations on the European market
- Data about the use and posology of preparations
- Preclinical aspects: phytopharmacology and toxicity
- Clinical use and therapeutic outcomes
- Safety aspects

The outcome of the discussions has led to a public statement.

## CONCLUSIONS

### Cardiovascular indications

The HMPC concluded that cardiovascular disorders for which traditional herbal preparations of *Viscum album* L., herba are used are not considered suitable for self medication. The HMPC also concluded that evidence of clinical efficacy was lacking and thus a well-established use indication was not supported.

### Cancer therapy

With regard to the use of *Viscum album* L., herba in cancer therapy, the HMPC concluded that this is outside the scope of the Directive 2001/83/EC as amended for traditional herbal medicinal products.

The HMPC also considered use in cancer therapy and concluded that the information available in the public domain was not sufficient to enable a well-established use indication to be supported.

A more extensive analysis and assessment of the regulatory overview, preclinical and toxicological data can be found in the assessment report on *Viscum album* L., herba:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal\\_med\\_000007.jsp&mid=WC0b01ac058001fa1d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000007.jsp&mid=WC0b01ac058001fa1d)