



15 January 2013  
EMA/HMPC/681468/2012  
Committee on Herbal Medicinal Products (HMPC)

## Public statement on *Adhatoda vasica* Nees, folium

Draft

Discussion in Working Party on Community Monographs and Community List (MLWP)	May 2012 November 2012
Adoption by HMPC for release for consultation	15 January 2013
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 April 2013
Rediscussion in MLWP	
Adoption by HMPC	

<b>Keywords</b>	Herbal medicinal products; HMPC; Public statements; <i>Adhatoda vasica</i> Nees, folium; Adhatodae vasicae folium; Malabar nut leaf
-----------------	---



# Public statement on *Adhatoda vasica* Nees, folium

## PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a Community herbal monograph on *Adhatoda vasica* Nees, folium as announced in the July 2011 HMPC meeting report. A call for the submission of scientific data was published on the EMA website with a submission period from 15 July 2011 until 15 November 2011.

A comprehensive literature search was conducted and available data, including information on products on the market in the European Union, were assessed in relation to the requirements laid down in Directive 2001/83/EC and its Annex I, in particular Article 1, Article 10a and Chapter 2a.

Evidence of traditional use originates mainly from India, where *A. vasica* has been used in the Ayurvedic tradition for a very long time. Detailed information on extraction solvents and/or posology for preparations used in the Indian traditional medicine is, however, incomplete.

No medicinal products containing *A. vasica* as a single active ingredient have been found within the EU. Although medicinal combination products containing *A. vasica* have been marketed in the EU for more than 15 years, it is not considered sufficient as basis for the establishment of a Community herbal monograph on *A. vasica* as a single active ingredient. European handbooks confirm the use of *A. vasica* in India, but no specific evidence of traditional medicinal use in Europe has been found.

During the assessment of the medicinal use of *A. vasica* information relating to possible abortive/anti-implantation and uterotonic effects was found. Further information on reproductive toxicity of *A. vasica* preparations is therefore considered necessary.

The HMPC/MLWP concluded that the following requirement for the establishment of a Community herbal monograph on traditional herbal medicinal products containing *Adhatoda vasica* Nees, folium is not fulfilled:

- the requirement laid down in Article 10a of Directive 2001/83/EC that the active substance has a recognised efficacy and an acceptable level of safety and that the period of well-established medicinal use has elapsed
- the requirement laid down in Article 16a(1)(d) of Directive 2001/83/EC that “the period of traditional use as laid down on Article 16c(1)(c) has elapsed”
- the requirement laid down in Article 16a(1)(b) of Directive 2001/83/EC that the herbal substance or herbal preparation is “exclusively for administration in accordance with a specified strength and posology”
- the requirement laid down in Article 16a(1)(e) of Directive 2001/83/EC that “the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience”

## CONCLUSIONS

Based on the currently available information on traditional use and concerns regarding reproductive safety, the HMPC is of the opinion that a Community herbal monograph on *Adhatoda vasica* Nees, folium cannot be established unless additional information is made available.

A link is provided to the page where to access the draft list of references available on *Adhatoda vasica*, Nees, folium.

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal\\_med\\_000180.jsp&mid=WC0b01ac058001fa1d](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000180.jsp&mid=WC0b01ac058001fa1d)