



London, 3 July 2008
Doc. Ref. EMEA/HMPC/283166/2007

**This document was valid from 03 July 2008 until June 2018.
It is now superseded by a [new version](#) adopted by the HMPC on
27 March 2018 and published on the EMA website.**

FINAL

COMMUNITY HERBAL MONOGRAPH ON *SAMBUCUS NIGRA* L., FLOS

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	July 2007 September 2007
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	7 September 2007
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 December 2007
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	March 2008 July 2008
ADOPTION BY HMPC	3 July 2008

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Sambucus nigra</i> L.; Sambuci flos; elder flower
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COMMUNITY HERBAL MONOGRAPH ON *SAMBUCUS NIGRA* L., FLOS

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1, 2}

<u>Well-established use</u>	<u>Traditional use</u>
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Sambucus nigra</i> L., flos (elder flower) i) Herbal substance - Dried flower ii) Herbal preparations A) Liquid extract, DER 1:1, extraction solvent: 25 % V/V ethanol B) Tincture, DER 1:5, extraction solvent: 25 % V/V ethanol

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	Herbal substance as herbal tea for oral use Herbal preparations in liquid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

¹ The material complies with the Eur. Ph. monograph (ref. 01/2005:1217)

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u> Herbal medicinal product traditionally used for the relief of early symptoms of common cold. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.
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4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adolescents over 12 years of age, adults, elderly</i> Herbal substance for tea preparation: 2-5 g 3 times daily A) Liquid extract: 3-5 ml 3 times daily B) Tincture: 10-25 ml 3 times daily The use is not recommended in children under 12 years of age (see section 4.4 Special warnings and precautions for use). Duration of use Not to be taken for more than 1 week. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Method of administration Oral use.
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity to the active substance.
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u> The use is not recommended in children under 12 years of age due to lack of adequate data. If symptoms worsen or when dyspnoea, fever or purulent sputum occurs during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For tinctures and extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.
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4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u> None reported.
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4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u> Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
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4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u> No studies on the effect on the ability to drive and use machines have been performed.
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4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u> None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.
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4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u> No case of overdose has been reported.
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5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u>
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

3 July 2008