EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2018
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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Sambucus nigra* L., flos

Final

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	July 2007 September 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	07 September 2007
End of consultation (deadline for comments)	15 December 2007
Re-discussion in MLWP	March 2008 July 2008
Adoption by HMPC Monograph (EMA/HMPC/283166/2007) AR (EMA/HMPC/283170/2007) List of references (EMA/HMPC/283842/2007) Overview of comments received during public consultation (EMA/HMPC/66605/2008) HMPC Opinion (EMA/HMPC/188139/2008)	3 July 2008
First systematic review	
Discussion in MLWP	September 2016 November 2016 February 2017 March 2017 May 2017 November 2017 January 2018
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Sambucus nigra* L.; Sambuci flos; elder flower

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BG (bulgarski): Черен бъз, цвят CS (čeština): květ bezu černého DA (dansk): Hyldeblomst DE (Deutsch): Holunderblüten EL (elliniká): ἀνθος ακτής EN (English): elder flower ES (español): saúco, flor de ET (eesti keel): leedriõis FI (suomi): mustaselja, kukka FR (français): sureau noir (fleur de) HR (hrvatski): bazgov cvijet HU (magyar): fekete bodza virág IT (italiano): Sambuco fiore	LT (lietuvių kalba): Šeivamedžių žiedai LV (latviešu valoda): Plūškoka ziedi MT (Malti): Fjura tas-Sambuka Sewda (or Sambuka tas-Siġra) NL (Nederlands): Vlierbloesem PL (polski): Kwiat bzu czarnego PT (português): sabugueiro, flor RO (română): floare de soc SK (slovenčina): kvet bazy čiernej SL (slovenščina): cvet črnega bezga SV (svenska): fläder, blomma IS (íslenska): NO (norsk): hylleblomst

European Union 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]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC *Sambucus nigra* L., flos (elder flower) i) Herbal substance As defined in the Ph. Eur. monograph. ii) Herbal preparations a) Comminuted herbal substance. b) Liquid extract (DER 1:1), extraction solvent: ethanol 25 % V/V c) Tincture (1:5) extraction solvent: ethanol 25 % V/V

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance or comminuted 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 declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

[2] The material complies with the Ph. Eur. Monograph (ref.: 1217).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used for the relief of early symptoms of common cold. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* a) Single dose: Herbal tea: 2-5 g of the herbal substance or comminuted herbal substance in 150 ml boiling water as a herbal infusion three times daily. Herbal tea: 3-6 g of the comminuted herbal substance in 200 ml water as a decoction divided in 2 single doses daily. b) Single dose: 2-5 ml three times daily c) Single dose: 10-25 ml three times daily The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use

[3] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1)

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children under 12 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. If dyspnoea, fever or purulent sputum occurs, 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.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No fertility data available.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	None known If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

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

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

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

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation / last revision

27 March 2018