



12 March 2013
EMA/HMPC/317319/2012
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Phaseolus vulgaris* L., fructus sine semine

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2012 September 2012 November 2012 January 2013
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	12 March 2013
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 July 2013
Rediscussion in Working Party on Community monographs and Community list (MLWP)	
Adoption by Committee on Herbal Medicinal Products (HMPC)	

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Phaseolus vulgaris</i> L., fructus sine semine; Phaseoli fructus sine semine; green bean pod
----------	--

BG (bългарски): фасул, плод без семена CS (čeština): fazolový plod bez semen DA (dansk): DE (Deutsch): (Samenfreie) Gartenbohnenhülsen EL (elliniká): Φασιόλου καρπός άνευ σπερμάτων EN (English): green bean (pod) ES (español): Judía ET (eesti keel): aedoa seemneteta kaun FI (suomi): tarhapapu (ilman siementä) FR (français): haricot (fruit sans graine d') HU (magyar): babhüvely IT (italiano):	LT (lietuvių kalba): Pupelių ankštys (be sėklų) LV (latviešu valoda): Pupiņas augļi (bez sēklām) MT (malti): Frott tal-Fażola NL (nederlands): gewone boon (peul zonder zaden) PL (polski): owośnia fasoli PT (português): feijão RO (română): SK (slovenčina): Plod fazule (bez semien) SL (slovenščina): plod fižola (brez semena) SV (svenska): bönskida (utan frö) <i>IS (islenska):</i> <i>NO (norsk):</i> hagebønnebelg (uten frø)
--	---



Community herbal monograph on *Phaseolus vulgaris* L., fructus sine semine

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 as amended <i>Phaseolus vulgaris</i> L., fructus sine semine (green bean pod) i) Herbal substance Not applicable. ii) Herbal preparations Comminuted herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

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 DAC 1986

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>Single dose</p> <p>Herbal tea: 2.5 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion, 2 - 6 times daily.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p>

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
	<p>The use in children and adolescents under 18 years of age is not recommended because of lack of data.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

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

Well-established use	Traditional use
	None reported.

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).

4.6. 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
	Not relevant.

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 as amended.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

Well-established use	Traditional use
	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

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

12 March 2013