5 April 2016
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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Crataegus* spp., folium cum flore

Final

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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Crataegus* spp., folium cum flore; Crataegi folium cum flore; hawthorn leaf and flower

BG (bulgarski): Глог, лист и цвят
CS (čeština): hlohový list s květem
DA (dansk): Hvidtjørn blad og blomst
DE (Deutsch): Weißdornblätter mit Blüten
EL (elliniká): φύλλο και άνθος κραταίγου
EN (English): hawthorn leaf and flower
ES (español): Espino blanco, hoja y flor de
ET (eesti keel): viirpuulehed koos õitega
FI (suomi): orapihlaja, lehti ja kukka
FR (français): Aubépine (sommité fleurie d')
HR (hrvatska):glogov list sa cvijetom
HU (magyar): galagonya virágos hajtásvég
IT (italiano): Biancospino foglia e fiore
LT (lietuvių kalba): Gudobelių lapai su žiedais
LV (latviešu valoda): Vilkābeļu lapas ar ziediem
MT (Malti): Werqa u Fjura taż-Żagħrun / ta' l-Anżalor
NL (Nederlands): Meidoorn
PL (polski): Kwiatostan głogu
PT (português): Pirliteiro, folha e flor
RO (română): frunză şi floare de păducel
SK (slovenčina): List hlohu s kvetom
SL (slovenščina): list in cvet gloga
SV (svenska): Hagtorn, blad och blomma
IS (íslenska):
NO (norsk): Hagtornblad og -blomst

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European Union herbal monograph on *Crataegus spp.*, folium cum flore

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 *Crataegus spp.*, folium cum flore (hawthorn leaf and flower) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Dry extract (DER 4-7:1), extraction solvent: methanol 70% V/V d) Dry extract (DER 4-7.1:1), extraction solvent: ethanol 45-70% V/V[3] e) Liquid extract (DER 1:0.9-1.1), extraction solvent: ethanol 45% V/V f) Liquid extract (DER 1:2), extraction solvent: ethanol 45% V/V g) Liquid extract (DER 1:19.2-20), extraction solvent: sweet wine h) Expressed juice from the fresh leaves and flowers (DER 1:0.63-0.9) i) Expressed juice from the fresh leaves and flowers (DER 1:0.9-1.1) j) Tincture (DER 1:3.5-4.5), extraction solvent: ethanol 35% V/V

[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.: 1432)
[3] The composition of the extraction solvent must be specified in the individual extract.

Well-established use	Traditional use
	k) Dry extract (DER 4-5:1), extraction solvent: water

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Powdered herbal substance in solid dosage forms for oral use. Herbal preparations e) to j) in liquid dosage forms for oral use. Herbal preparations c), d) and k) in solid or liquid dosage forms 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
	Indication 1) Traditional herbal medicinal product used to relieve symptoms of temporary nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety) after serious conditions have been excluded by a medical doctor. Indication 2) Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration[4]

Well-established use	Traditional use
	Posology Indication 1) *Adults and elderly* a) Herbal tea: 1-2 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion up to 4 times daily (max. 6 g) b) single dose: 190-350 mg daily dose: 570-1750 mg c) single dose: 80-300 mg daily dose: 240-900 mg d) single dose: 80-450 mg daily dose: 240-900 mg e) single dose: 0.56-1.25 g daily dose: 1.68-3.75 g f) single dose: 1.84 g daily dose: 5.52 g g) single dose: 8.24 g daily dose: 16.5 g h) single dose: 7 ml daily dose: 21 ml i) single dose: 2.4 ml daily dose: 7.5 ml j) single dose: 1.68 g daily dose: 5.1 g The use in children and adolescents under 18 years of age is not recommended (see section 4.4. 'Special warnings and precautions for use'). Indication 2) *Adolescents, adults and elderly* b) single dose: 190-350 mg daily dose: 570-1750 mg k) single dose: 250 mg daily dose: 750–1000 mg The use in children under 12 years of age is not recommended (see section 4.4. 'Special warnings

[4] 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).

Well-established use	Traditional use
	and precautions for use'). **Duration of use** Indication 1 and 2) 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. **Method of administration** Oral use.

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
	Indication 1) The use in children and adolescents under 18 years of age is not recommended because of concerns requiring medical advice. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. If the ankles or legs become swollen, when pain occurs in the region of the heart, which may spread out to the arms, upper abdomen or the area around the neck, or in case of respiratory distress (dyspnea), a doctor or a qualified health care practitioner should be consulted immediately. 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. Indication 2) 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

Well-established use	Traditional use
	medicinal product, a doctor or a qualified health care practitioner should be consulted.

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 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. The dry extract (DER 4-6.6:1, ethanol 45% m/m) did not reveal any genotoxicity in several tests (*in vitro*: Ames test, mouse lymphoma assay, cytogenetic analysis in cultured human lymphocytes; *in vivo*: micronucleus test). Tests on genotoxicity have not been performed for all the other preparations of the monograph. Adequate tests on reproductive toxicity have not been performed. Tests on carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation / last revision

5 April 2016