EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

**Draft**

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| Discussion in Working Party on European Union monographs and European Union list (MLWP) | March 2014<br>May 2014<br>July 2014 |
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| **Keywords** | Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Crataegus* spp.; folium cum flore; hawthorn leaf and flower |

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|---|---|
| BG (bălgarski): Глог, лист и цвят<br>CS (čeština): hlohový list s květem<br>DA (dansk): Hvidtjørn blad og blomst<br>DE (Deutsch): Weißdornblätter mit Blüten<br>EL (elliniká): φύλλο και άνθος κραταίγου<br>EN (English): Hawthorn Leaf and Flower<br>ES (espanol): Espino blanco, hoja y flor de<br>ET (eesti keel): viirpuulehed koos õitega<br>FI (suomi): orapihlaja, lehti ja kukka<br>FR (français): Aubépine (sommité fleurie d')<br>HU (magyar): Galagonya virágos hajtásvég<br>HR (hrvatska):glogov list sa cvijetom<br>IT (italiano): Biancospino foglia e fiore | LT (lietuvių kalba): Gudobelių lapai su žiedais<br>LV (latviešu valoda): Vilkābeļu lapas ar ziediem<br>MT (malti): Werqa u Fjura taż-Żagħrun / ta' l-Anżalor<br>NL (nederlands): Meidoorn<br>PL (polski): Kwiatostan głogu<br>PT (português): Pirliteiro, folha e flor<br>RO (română): frunză şi floare de păducel<br>SK (slovenčina): Hlohový list s kvetom<br>SL (slovenščina): list in cvet gloga<br>SV (svenska): Hagtorn, blad och blomma<br>*IS (íslenska)*:<br>*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<br><br>*Crataegus spp.*, folium cum flore (hawthorn leaf and flower)<br><br>i) Herbal substance<br><br>Not applicable.<br><br>ii) Herbal preparations<br><br>a) Comminuted herbal substance<br><br>b) Powdered herbal substance<br><br>c) Dry extract (DER 4-7:1), extraction solvent methanol 70% V/V<br><br>d) Dry extract (DER 4-7.1:1), extraction solvent ethanol 45-70% V/V[3]<br><br>e) Liquid extract (DER 1:1), extraction solvent ethanol 45% V/V<br><br>f) Liquid extract (DER 1:0.9-2), extraction solvent ethanol 45% V/V<br><br>g) Liquid extract (DER 1:19.2-20), extraction solvent sweet wine<br><br>h) Pressed fresh juice (DER 1:0.63-0.9)<br><br>i) Pressed fresh juice (DER 1:0.9-1.1)<br><br>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.: 01/2010:1432)
[3] The composition of the extraction solvent must be specified in the individual extract.

# 3. Pharmaceutical form

| Well-established use | Traditional use |
|---|---|
| | Comminuted herbal substance as herbal tea for oral use.<br><br>Powdered herbal substance in solid dosage forms for oral use.<br><br>Herbal preparations e) to j) in liquid dosage forms for oral use.<br><br>Herbal preparations c) and d) in solid or liquid dosage forms for oral use.<br><br>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)<br><br>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.<br><br>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.<br><br>Indication 2)<br><br>Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep.<br><br>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**<br>Indication 1)<br>*Adults and elderly*<br>a) single dose: 1-2 g<br>daily dose: 3-4 times daily (max. 6 g)<br>herbal tea: 1-2 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion<br>b) single dose: 190-350 mg<br>daily dose: 570-1750 mg<br>c) single dose: 80-300 mg<br>daily dose: 240-900 mg<br>d) single dose: 80-450 mg<br>daily dose: 240-900 mg<br>e) single dose: 0.56 g<br>daily dose: 1.6-2.3 g<br>f) single dose: 1.2-1.8 g<br>daily dose: 3.6-5.5 g<br>g) single dose: 8.2 g<br>daily dose: 16.5 g<br>h) single dose: 7 ml<br>daily dose: 21 ml<br>i) single dose: 2.4 ml<br>daily dose: 7.5 ml<br>j) single dose: 1.6 g<br>daily dose: 5.1 g<br>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').<br>Indication 2)<br>*Adolescents, adults and elderly*<br>b) single dose: 190-350 mg<br>daily dose: 570-1750 mg<br>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').<br><br>**Duration of use**<br><br>Indication 1)<br><br>If the symptoms persist for more than 4 weeks, a doctor or a qualified health care practitioner should be consulted.<br><br>Indication 2)<br><br>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.<br><br>**Method of administration**<br><br>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)<br><br>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.<br><br>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.<br><br>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.<br><br>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. |

| Well-established use | Traditional use |
|---|---|
| | Indication 2)<br><br>The use in children under 12 years of age has not been established due to lack of adequate data.<br><br>If the symptoms worsen during the use of the 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.<br><br>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.<br><br>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.<br><br>The dry extract (4-6.6:1, ethanol 45% m/m) did not reveal any genotoxicity in several tests (*in-vitro*: Ames test (incomplete), mouse lymphoma assay, cytogenetic analysis in cultured human lymphocytes; *in-vivo*: micronucleus test).<br>Tests on genotoxicity have not been performed for all the other preparations of the monograph.<br><br>Tests on reproductive toxicity and carcinogenicity have not been performed. |

# 6. Pharmaceutical particulars

| Well-established use | Traditional use |
|---|---|
| | Not applicable. |

# 7. Date of compilation/last revision

30 September 2014