



28 January 2015
EMA/HMPC/685372/2014
Committee for Herbal Medicinal Products (HMPC)

European Union list entry on *Crataegus* spp., folium cum flore

Draft

Discussion in Working Party on European Union monographs and European Union list (MLWP)	September/October 2014 November 2014
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	28 January 2015
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 May 2015
Rediscussion in MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; European Union list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Crataegus</i> spp.; Crataegi folium cum flore; hawthorn leaf and flower
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Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products on *Crataegus* spp., folium cum flore

Scientific name of the plant	
<i>Crataegus</i> spp.	
Botanical family	
Rosaceae	
Herbal substance	
Not applicable.	
Common name of herbal substance in all EU official languages	
BG (bългарски): 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 κραταιγίου 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') HU (magyar): Galagonya virágos hajtásvég HR (hrvatska): glogov list sa cvijetom 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 și floare de păducel SK (slovenčina): Hlohový list s kvetom SL (slovenščina): list in cvet gloga SV (svenska): Hagtorn, blad och blomma <i>IS (islenska):</i> <i>NO (norsk):</i> Hagtornblad og -blomst
Herbal preparation(s)	
Dry extract (DER 4-6.6: 1), extraction solvent ethanol 45% m/m	
European Pharmacopoeia monograph reference	
Hawthorn leaf and flower - <i>Crataegi folium cum flore</i> (01/2010:1432)	
Indication(s)	
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.	
Type of tradition	
European	
Specified strength	
Please see 'Specified posology'.	

Specified posology
<p><i>Adults and Elderly</i></p> <p>single dose: 80-450 mg daily dose: 240-900 mg</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 'Special warnings and precautions for use').</p>
Route of administration
Oral use.
Duration of use or any restrictions on the duration of use
If the symptoms persist for more than 4 weeks, a doctor or a qualified health care practitioner should be consulted.
Any other information necessary for the safe use
<p>Contraindications</p> <p>Hypersensitivity to the active substance.</p> <p>Special warnings and precautions for use</p> <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate 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> <p>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.</p> <p>Interactions with other medicinal products and other forms of interaction</p> <p>None reported.</p> <p>Fertility, Pregnancy and lactation</p> <p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p> <p>Effects on ability to drive and use machines</p> <p>No studies on the effect on the ability to drive and use machines have been performed.</p> <p>Undesirable effects</p> <p>None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

Overdose

No case of overdose has been reported.

Pharmaceutical particulars [If necessary]

Not applicable.

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [If necessary for the safe use of the product]

Not applicable.

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