



7 July 2015
EMA/HMPC/715092/2013
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Carum carvi* L., fructus

Final

Discussion in Working Party on European Union monographs and list (MLWP)	November 2013 May 2014 July 2014 September 2014
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	24 November 2014
Start of public consultation	
End of consultation (deadline for comments)	15 March 2015
Rediscussion in MLWP	May 2015
Adoption by HMPC	7 July 2015

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Carum carvi</i> L., fructus; Carvi fructus; Caraway fruit
----------	--

BG (bulgarski): ким, плод CS (čeština): kmínový plod DA (dansk): Kommen DE (Deutsch): Kümmel EL (elliniká): καρπός κάρου EN (English): Caraway fruit ES (español): Alcaravea, fruto de ET (eesti keel): köömen FI (suomi): kumina FR (français): Carvi (fruit de) HR (hrvatski): kimov plod HU (magyar): Köménytermés IT (italiano): Carvi (cumino dei prati) frutto	LT (lietuvių kalba): Kmyņu vaisiai LV (latviešu valoda): Ķīmenes augļi MT (Malti): Frotta tal-karwija NL (Nederlands): Karwijzaad PL (polski): Owoc kminku PT (português): Alcarávia RO (română): fruct de chimen SK (slovenčina): Plod rasce SL (slovenščina): plod navadne kumine SV (svenska): Kummin, frö <i>IS (íslenska):</i> <i>NO (norsk):</i> Karve
--	---



European Union herbal monograph on *Carum carvi* L., fructus

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>Carum carvi</i> L., fructus (Caraway fruit) i) Herbal substance As defined in the Ph. Eur. monograph. ii) Herbal preparations Comminuted herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance or 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 for the symptomatic relief of digestive disorders such as bloating and flatulence. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

¹The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

²The material complies with the Ph. Eur. monograph (ref.: 1080).

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p><i>Single dose</i></p> <p>Herbal tea: 0.5-2 g of the herbal substance or comminuted herbal substance in 150 ml of boiling water as a herbal infusion, 1-3 times daily</p> <p>The use in children under 12 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
	<p>Hypersensitivity to the active substance, to other plants of the Apiaceae (Umbelliferae) family (fennel, anise, celery, coriander and dill), to mugwort or to birch.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>The use in patients with liver disease, cholangitis, achlorhydria, gallstones and any other biliary disorders is not recommended.</p> <p>If the symptoms worsen during the use of the</p>

³For 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
	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. Adequate 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

7 July 2015