EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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Rediscussion in MLWP	
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BG (bălgarski): ким, плод	LT (lietuvių kalba): Kmynų vaisiai
CS (čeština): Kmínový plod	LV (latviešu valoda): Ķimenes augļi
DA (dansk): Kommen	MT (malti): Frotta tal-karwija
DE (Deutsch): Kümmel	NL (nederlands): Karwijzaad, kummel
EL (elliniká): καρπός κάρου	PL (polski): Owoc kminku zwyczajnego
EN (English): Caraway fruit	PT (português): Alcarávia
ES (espanol): Alcaravea, fruto de	RO (română): Fruct de chimen
ET (eesti keel): Köömen	SK (slovenčina): Rascový plod
FI (suomi): kumina	SL (slovenščina): Plod navadne kumine
FR (français): Carvi (fruit de)	SV (svenska): Kummin
HR (hrvatski): plod kima	*IS (íslenska)*:
HU (magyar): Köménytermés	*NO (norsk)*: Karve
IT (italiano): Carvi (cumino dei prati) frutto	

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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 *Carum carvi* 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.

[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.: 01/2008:1080).

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* *Single dose* 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. The use in children 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** 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, to other plants of the Apiaceae (Umbelliferae) family (fennel, anise, celery, coriander and dill), to mugwort or to birch.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 12 years of age has not been established due to lack of adequate data. The use in patients with liver disease, cholangitis, achlorhydria, gallstones and any other biliary disorders is not recommended. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health

[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).

Well-established use	Traditional use
	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

Well-established use	Traditional use
	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[4]

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

24 November 2014