EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2014
EMA/HMPC/715094/2013
Committee on Herbal Medicinal Products (HMPC)

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

Draft

Discussion in Working Party on European Union monographs and European Union list (MLWP)	November 2013 May 2014 July 2014 30 September 2014
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	24 November 2014
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 March 2015
Rediscussion in MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Carum carvi* L., aetheroleum; Carvi aetheroleum; Caraway oil

BG (bălgarski): ким, плод CS (čeština):Kmínová silice DA (dansk): Kommenolie DE (Deutsch): Kümmelöl EL (elliniká): αιθέριο έλαιο κάρου EN (English): Caraway oil ES (espanol): Alcaravea, aceite esencial de ET (eesti keel): Köömneõli FI (suomi): Kuminaöljy FR (français): Carvi (huile essentielle de) HR (hrvatska): Kimovo eterično ulje HU (magyar): Köményolaj IT (italiano): Carvi (cumino dei prati) essenza	LT (lietuvių kalba): Kmynų eterinis aliejus LV (latviešu valoda): Ķimenes augļi MT (malti): Żejt tal-karwija NL (nederlands): Karwijzaadolie, Karwijolie PL (polski): Kminek zwyczajny PT (português): Óleo essencial de alcarávia RO (română): Ulei volatil de chimen SK (slovenčina): Rascová silica SL (slovenščina): Plod navadne kumine SV (svenska): Kumminolja *IS (íslenska)*: *NO (norsk):* Karveolje

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

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., aetheroleum (caraway oil) i) Herbal substance Not applicable. ii) Herbal preparation Essential oil

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparation in liquid dosage form for oral use. Herbal preparation in semi-solid dosage form for cutaneous 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

[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) and the herbal preparation complies with the Ph. Eur. monograph (ref.: 01/2008:1817).

Well-established use	Traditional use
	bloating and flatulence. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology **Oral use** *Adults and elderly* *Daily dose* 0.15-0.3 ml of the herbal preparation divided in 1-3 doses daily. The oral use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Cutaneous use** *Infants, children, adolescents, adults and elderly* Daily dose 2% semi-solid preparations: to be applied once daily as a thin layer on the abdominal area. **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. Cutaneous use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to other plants of the Apiaceae (Umbelliferae) family (fennel, anise, celery, coriander and dill).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Cutaneous use The product should not be used on broken skin, around the eyes or on mucous membranes. **Oral use** The oral use in children and adolescents under 18 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. **Oral and Cutaneous use** 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. 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

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[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