



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Carum carvi* L., aetheroleum (EMA/HMPC/715094/2013)

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Carum carvi* L., fructus as released for public consultation on 24 November 2014 until 15 March 2015.

	Organisations and/or individuals
1	Association of the European Self-Medication Industry (AESGP)



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
AESGP	<p>AESGP welcomes the development of the above-mentioned Community herbal monograph which, by providing harmonised assessment criteria for Carum-containing products, should facilitate mutual recognition in Europe.</p> <p>We have the following specific comments.</p>	

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
4.2. Posology and method of administration	AESGP	<p><u>Comment:</u></p> <p>Therapeutic experience is available on the oral use of caraway oil in India. The product Bonnispez drops is the combination of the essential oils of Carum carvi, Carum copticum and Zingiber officinale. It is indicated for the treatment of infants and children with infantile colic, flatulence and abdominal bloating.</p> <p>Safety and tolerability of the product in the paediatric population has been shown in two open label clinical trials with 128 infants and children aged under 3 years. The children took Bonnispez drops for abdominal colic for 5 days. The dosage was initially 4 drops, then 2 drops 3-times daily, corresponding to daily doses of 0.25 up to maximum of 0.4 ml per day. The authors conclude that Bonnispez drops are clinically safe and effective in the management of abdominal colic in infants and children (Bahrat et</p>	Not endorsed. The oral use in children and adolescents under 18 years of age has not been established due to lack of adequate data. The provided references refer to a combination product. In addition the provided references are published in 2007. Thus, traditional medicinal use according to Directive 2004/24/EC is not considered fulfilled for oral administration of caraway oil to children and adolescents under 18 years of age.

Section number and heading	Interested party	Comment and Rationale	Outcome
		<p>al. 2007, Gosh et al. 2007). Documented therapeutic experience with this product in small children delivers evidence for the safety and tolerability of caraway oil as active substance. Overall, caraway oil may safely be used at recommended dosages of 0.15 to 0.3 ml per day in adolescents aged from 12 to 18 years.</p> <p><u>Proposed change:</u></p> <p>Oral use <i>Adolescents, adults and elderly</i> <i>Daily dose</i> 0.15-0.3 ml of the herbal preparation divided in 1-3 doses daily.</p>	
4.4. Special warnings and precautions for use	AESGP	<p><u>Comment:</u></p> <p>Therapeutic experience is available on the oral use of caraway oil in India. The product Bonnispaz drops is the combination of the essential oils of <i>Carum carvi</i>, <i>Carum copticum</i> and <i>Zingiber officinale</i>. It is indicated for the treatment of infants and children with infantile colic, flatulence and abdominal bloating.</p> <p><u>Proposed change:</u></p> <p>Oral use The oral use in children under 12 years of age has not been established due to lack of adequate data.</p>	Not endorsed. See comments above.

References (not contained in EMA/HMPC/242200/2014 and therefore supplied as copies):

1. Bharat JP, Prasad SR, Mitra SK. Evaluation of efficacy and safety of Bonnispaz drops in abdominal colic of infants and children. The antiseptic, Oct 2007.
2. Gosh SP, Prasad SR, Mitra SK. Bonnispaz drops. Evaluation of its efficacy and safety in abdominal colic of infants and children. Medicine Update 15(4), 2007.