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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

**COMMUNITY LIST ENTRY ON
PIMPINELLA ANISUM L., FRUCTUS**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	July 2007
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	5 July 2007
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 October 2007
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Pimpinella anisum</i> L; Anisi fructus; aniseed
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**ENTRY TO COMMUNITY LIST OF HERBAL SUBSTANCES, PREPARATIONS AND
COMBINATIONS THEREOF FOR USE IN
TRADITIONAL HERBAL MEDICINAL PRODUCTS:
*PIMPINELLA ANISUM L., FRUCTUS***

Scientific name of the plant	
<i>Pimpinella anisum L.</i>	
Botanical family	
Apiaceae	
Herbal substance	
Aniseed	
Common name in all EU official languages of herbal substance	
BG (bългарski):	IT (italiano): Anice, frutto (Anice verde)
CS (čeština): anýzový plod	LT (lietuvių kalba):
DA (dansk):	LV (latviešu valoda):
DE (Deutsch): Anis	MT (Malti):
EL (elliniká):	NL (Nederlands): Anijsvrucht
EN (English):	PL (polski): owoc anyżu
ES (español): Anís, fruto de	PT (português):
ET (eesti keel): aniisivilili	RO (română):
FI (suomi): anis	SK (slovenčina): Anízový plod
FR (français): fruit d'Anis (fruit d'anis vert)	SL (slovenščina): plod vrtnega janeža
HU (magyar):	SV (svenska):
	<i>IS (íslenska): anísfræ</i>
	<i>NO (norsk):</i>
Herbal preparation(s)	
Dried aniseed, comminuted or crushed	
European Pharmacopoeia monograph reference	
01/2005:0262	
Indication(s)	
<p>a) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.</p> <p>b) Traditional herbal medicinal product used as an expectorant in cough associated with cold.</p>	
The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.	

Type of tradition
European
Specified strength
See Specified posology
Specified posology
<p><i>Adolescents over 12 years of age, adults, elderly:</i> Indications a) and b) 1 to 3.5 g of whole or (freshly²) comminuted or crushed aniseed in 150 ml of water as a herbal tea 3 times daily</p> <p>The use is not recommended in children under 12 years of age (see below ‘Special warnings and precautions for use’).</p>
Route of administration
Oral use
Duration of use or any restrictions on the duration of use
<p>Not to be taken for more than two weeks.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>
Any other information necessary for the safe use
<p>Contraindications</p> <p>Hypersensitivity to the active substance or to Apiaceae (Umbelliferae) (caraway, celery, coriander, dill and fennel) or to anethole.</p> <p>Special warnings and precautions for use</p> <p>The use is not recommended in children under 12 years of age due to the lack of adequate data for safety assessment.</p> <p>Interactions with other medicinal products and other forms of interaction</p> <p>None reported.</p> <p>Pregnancy and lactation</p> <p>There are no data from the use of aniseed in pregnant patients.</p> <p>It is unknown if aniseed constituents are excreted in human breast milk.</p> <p>In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</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>

² For commercial preparations of comminuted or crushed aniseed the applicant must carry out appropriate stability testing related to the content of essential oil components

Undesirable effects

Allergic reactions affecting the skin or the respiratory system may occur. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

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.