European Medicines Agency
Evaluation of Medicines for Human Use

London, 31 October 2007
Doc. Ref. EMEA/HMPC/202966/2007

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *AVENA SATIVA* L., HERBA

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2007 July 2007 September 2007 October 2007
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	31 October 2007
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 February 2008
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

Comments should be provided using this template to hmpc.secretariat@emea.europa.eu
Fax: +44 20 75 23 70 51

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Avena sativa* L.; Avenae herba; oat herb

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

COMMUNITY HERBAL MONOGRAPH ON *AVENA SATIVA* L., HERBA

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 *Avena sativa* L., herba (oat herb) i) Herbal substance Dried aerial parts harvested before flowering ii) Herbal preparations - Comminuted herbal substance Liquid extract (1:5; ethanol 45% v/v) prepared from the fresh aerial parts of the plant harvested during the flowering period

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal preparation in liquid dosage form or as a herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents over 12 years of age, adults, elderly* Single dose Comminuted herbal substance: 3 g Liquid extract (1:5; ethanol 45% v/v): 0.2 to 5 ml up to 3 times daily. The use is not recommended in children under 12 years of age (see section 4.4 Special warnings and precautions for use). **Duration of use** Not to be taken for more than 2 weeks. If the symptoms persist 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 and to Avena species.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use is not recommended in children under 12 years of age due to the lack of adequate data. Caution is advised when used in patients with coeliac disease because data on the protein content are missing. For liquid extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	Concomitant use with synthetic sedatives is not recommended unless advised by a doctor.

4.6. 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.

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. May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

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. 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

31 October 2007