



London, 31 October 2007  
Doc. Ref. EMEA/HMPC/368600/2007

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

**DRAFT**

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

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

Comments should be provided using this [template](#) to [hmpc.secretariat@emea.europa.eu](mailto:hmpc.secretariat@emea.europa.eu)  
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**KEYWORDS**

Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Avena sativa* L.; Avenae fructus; oat fruit

## COMMUNITY HERBAL MONOGRAPH ON *AVENA SATIVA* L., FRUCTUS

### 1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION<sup>1</sup>

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Avena sativa</i> L., fructus (oat fruit) cleaned and sieved after harvesting</p>

### 3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Dried seeds comminuted to oat flour 'Colloidal oatmeal'<sup>2</sup></p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

### 4. CLINICAL PARTICULARS

#### 4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Traditional herbal medicinal product for the symptomatic treatment of minor inflammations of the skin (such as sunburn) and as an aid in healing of minor wounds.</p> <p>The product is a traditional herbal medicinal product for use in specified indication(s) exclusively based upon long-standing use.</p>

<sup>1</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

<sup>2</sup> It complies with the USP monograph [USP 30 (1990)].

#### 4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u>  <b>Posology</b>  A) For a bath of 150 to 200 litre 60 g Avena flour is prescribed; for children 50% of this dose is used.  B) Colloidal extracts of flour are used in concentrations up to 20 – 30%, mixed with vehiculum.  C) Liquid paraffin with 5% oatmeal. There is no restriction in age.  <b>Duration of use</b>  If the symptoms persist after 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.  <b>Method of administration</b>  Topical use.
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#### 4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u>  Hypersensitivity to the active substance and to Avena species.
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#### 4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u>  Not applicable.
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#### 4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u>  None reported.
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#### 4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u>  There are no data on use during pregnancy or lactation. No concern has arisen about any malformation in humans.
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#### 4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u> No data available.
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#### 4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u> Skin reactions occur frequently in atopic patients and in patients with contact dermatitis.  If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.
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#### 4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u> No case of overdose has been reported.
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### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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#### 5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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#### 5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u> 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.
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**6. PHARMACEUTICAL PARTICULARS**

<u>Well-established use</u>	<u>Traditional use</u>
	Not applicable.

**7. DATE OF COMPILATION/LAST REVISION**

31 October 2007