European Medicines Agency
Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

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

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	September 2007 October 2007
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REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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

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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[1]

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., fructus (oat fruit) cleaned and sieved after harvesting

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Dried seeds comminuted to oat flour 'Colloidal oatmeal' [2] 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 treatment of minor inflammations of the skin (such as sunburn) and as an aid in healing of minor wounds. The product is a traditional herbal medicinal product for use in specified indication(s) exclusively based upon long-standing use.

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[2] It complies with the USP monograph [USP 30 (1990)].

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology 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. **Duration of use** 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. **Method of administration** Topical 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
	Not applicable.

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

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	There are no data on use during pregnancy or lactation. No concern has arisen about any malformation in humans.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No data available.

4.8. Undesirable effects

Well-established use	Traditional use
	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.

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