



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Herbal Medicinal Products (HMPC)

Template for a European Union list entry

Final

Adoption by Committee on Herbal Medicinal Products (HMPC)	11 January 2007
Revisions 1 and 2 adopted by HMPC	8 March 2007 5 July 2007
Revision 3 adopted by HMPC	6 March 2008
Revision 4 adopted by HMPC	15 July 2010
Revision 5 agreed by ORGAM DG	January 2014 May 2014 February 2014 September 2014
Revision 5 agreed by MLWP	July 2014
Revision 5 adopted by HMPC	September 2014

- *This template should be read in conjunction with the following document:*

'Procedure for the preparation of an entry to the European Union list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMEA/HMPC/57137/2007).

- *All instruction notes (in green) must be deleted before finalising the list entry.*

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<date>
<doc ref>
Committee for Herbal Medicinal Products (HMPC)

European Union list entry on <combination(s) of> <plant>, <plant part>, <and> <herbal preparation(s)>

Insert botanical name of the plant according to the binomial system (genus, species, variety and author), [comma] the plant part in Latin.

<Draft><Final>

Discussion in Working Party on European Union monographs and European Union list (MLWP)	
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	
Start of public consultation	
End of consultation (deadline for comments ¹). <Comments should be provided using this template to hmpc.secretariat@ema.europa.eu >	
Re-discussion in MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; European Union list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; traditional use; <plant> <i>Insert botanical name of the plant according to the binomial system (genus, species, variety and author)</i> ; <Latin term for herbal substance>; <English common name of herbal substance>
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¹ No comments were received during the period of public consultation.

Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products on <plant>, <plant part>, <and> <herbal preparations>

Scientific name of the plant	
xxx	
Botanical family	
xxx	
Herbal substance	
<xxx> <Not applicable.>	
Common name of <herbal substance><herbal preparation²> in all EU official languages	
BG (bulgarski): CS (čeština): DA (dansk): DE (deutsch): EL (elliniká): EN (English): ES (español): ET (eesti keel): FI (suomi): FR (français): HR (hrvatski): HU (magyar):	IT (italiano): LT (lietuvių kalba): LV (latviešu valoda): MT (Malti): NL (Nederlands): PL (polski): PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): IS (islenska): NO (norsk):
<Herbal preparation(s)> <Combination(s) of herbal substance(s) and/or herbal preparation(s)>	
<Comminuted herbal substance> <Powdered herbal substance> <Dry extract (DER x-y: 1), extraction solvent xxx> <Liquid extract (DER 1: x-y), extraction solvent xxx> <Tincture (ratio of herbal substance to extraction solvent <1:5><1:10>), extraction solvent xxx>	
<European><National> Pharmacopoeia monograph reference	
<xxx> <Not applicable.>	
Indication(s)	
<Indication 1>	

² In case the list entry refers to an herbal preparation different from those listed in the list entry of the herbal substance e.g. essential oils

Traditional herbal medicinal product <used> for xxx <after serious conditions have been excluded by a medical doctor>.>

<Indication 2)

Traditional herbal medicinal product <used> for xxx <after serious conditions have been excluded by a medical doctor>.>

The product is a traditional herbal medicinal product for use in <the specified indication><specified indications> exclusively based upon long-standing use.

Type of tradition

<European> <Chinese> <Ayurvedic> <Anthroposophic>

Specified strength

<Please see 'Specified posology'.>

Specified posology

<Children> <Adolescents> <Adults> <Elderly>

<Single dose> <Daily dose><Average daily dose>

Please see instructions and standard statements in the HMPC template for European Union herbal monographs (section 4.2, Traditional use part).

Route of administration

Please see instructions and standard statements in the HMPC template for European Union herbal monographs (under 'Route of administration' in section 4.2, Traditional use part).

Duration of use or any restrictions on the duration of use

Please see instructions and standard statements in the HMPC template for European Union herbal monographs (under 'Duration of use' in section 4.2, Traditional use part).

Any other information necessary for the safe use

Contraindications

Please see instructions and standard statements in the HMPC template for European Union herbal monographs (section 4.3, Traditional use part).

Special warnings and precautions for use

Please see instructions and standard statements in the HMPC template for European Union herbal monographs (section 4.4, Traditional use part).

Interactions with other medicinal products and other forms of interaction

<None reported.>

Fertility, pregnancy and lactation

Please see instructions and standard statements in the HMPC template for European Union herbal monographs (section 4.6, Traditional use part).

Effects on ability to drive and use machines

Please see instructions and standard statements in the HMPC template for European Union herbal monographs (section 4.7, Traditional use part).

Undesirable effects

Please see instructions and standard statements in the HMPC template for European Union herbal monographs (section 4.8, Traditional use part).

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.>

Date of compilation/Last revision

<Date month year>