



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Symphytum officinale* L., radix

Draft

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BG (bългарски): Черен оман, корен CS (čeština): kostivalový kořen DA (dansk): Kulsukkerrod DE (Deutsch): Beinwellwurzel EL (elliniká): ρίζα συμφύτου EN (English): Comfrey Root ES (español): Consuelda mayor, raíz de ET (eesti keel): varemerohujuur FI (suomi): FR (français): Grande consoude (racine de) HU (magyar): Feketenadálytő gyökér IT (italiano): Consolida maggiore radice	LT (lietuvių kalba): LV (latviešu valoda): Tausaknes saknes MT (malti): NL (nederlands): Smeerwortel PL (polski): Korzeń żywokostu PT (português): Consolda-maior, raiz RO (română): rădăcină de tătăneasă SK (slovenčina): Koreň kostihoja SL (slovenščina): korenina navadnega gabeza SV (svenska): Valörtsrot IS (íslenska): NO (norsk): Valurtrot
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Community herbal monograph on *Symphytum officinale* L., radix

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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Symphytum officinale</i> L., radix (comfrey root)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Liquid extract (DER 2:1), extraction solvent ethanol 65% V/V.</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparations in semi-solid dosage forms for cutaneous use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product used for the symptomatic treatment of minor sprains and bruises.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication</p>

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

² The material complies with the British Herbal Pharmacopoeia, 1996 (British Herbal Pharmacopoeia 1996. British Herbal Medicine Association, Bournemouth, 1996. pp. 62-63.)

Well-established use	Traditional use
	exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>Liquid extract in an ointment base (100 g ointment contains 10 g extract): apply the ointment 2 times daily.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>If the symptoms persist longer than 10 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Cutaneous use.</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>Should be applied only on intact skin.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>For 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</p>

Well-established use	Traditional use
	included.

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

Well-established use	Traditional use
	None reported.

4.6. Fertility, 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
	Not relevant.

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
	<p>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.</p> <p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p> <p>Adverse reactions were not observed in clinical studies, but animal studies suggest that excessive amount of pyrrolizidine alkaloids in medicinal products may be hepatotoxic. The content of pyrrolizidine alkaloids should be limited according to national provisions.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

12 July 2011