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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Symphytum officinale* L., radix

### Final

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# European Union 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<sup>1,2</sup>

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 Not applicable.</p> <p>ii) Herbal preparations Liquid extract prepared by extraction with ethanol 65% (V/V) followed by partial evaporation and adjustment to a DER 2:1</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 relief of minor sprains and bruises.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication 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> Detailed specification for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia.

#### 4.2. Posology and method of administration

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adults and elderly:</i></p> <p>Single dose for semi-solid dosage forms (10% liquid extract): apply a thin layer, 2 times a daily</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precaution for use').</p> <p><b>Duration of use</b></p> <p>Not to be used for more than 10 days.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Method of administration</b></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>Not to be applied to broken or irritated skin.</p> <p>Avoid contact with the eyes or mucous membranes.</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>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p>

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

<b>Well-established use</b>	<b>Traditional use</b>
	None reported.

#### **4.6. Fertility, pregnancy and lactation**

<b>Well-established use</b>	<b>Traditional use</b>
	<p>Safety during pregnancy and lactation has not been established. Studies with isolated pyrrolizidine alkaloids from the plant part in animals have shown reproductive toxicity (see section 5.3 'Preclinical safety data').</p> <p>In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

#### **4.7. Effects on ability to drive and use machines**

<b>Well-established use</b>	<b>Traditional use</b>
	Not relevant.

#### **4.8. Undesirable effects**

<b>Well-established use</b>	<b>Traditional use</b>
	<p>None known.</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

#### **4.9. Overdose**

<b>Well-established use</b>	<b>Traditional use</b>
	No case of overdose has been reported.

### **5. Pharmacological properties**

#### **5.1. Pharmacodynamic properties**

<b>Well-established use</b>	<b>Traditional use</b>
	Not required as per Article 16c(1)(a)(iii) of

Well-established use	Traditional use
	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>Animal studies suggest that pyrrolizidine alkaloids are hepatotoxic after oral administration. Several pyrrolizidine alkaloids and pyrrolizidine alkaloid derivatives have been shown to produce genotoxic effects in cell cultures after metabolic activation. In rats, after oral administration appropriately low repeated doses of several alkaloids have been shown to induce tumours and in some studies, a single dose has been carcinogenic.</p> <p>In rats, after oral application of the pyrrolizidine alkaloid lasiocarpine given at doses of 35 mg/kg during pregnancy, foetal hepatotoxicity was observed.</p> <p>Until now only rudimentary data concerning absorption of PAs through the skin exist.</p> <p>The amount of PA within the daily dose should be limited to below &lt;math&gt;0.35 \mu\text{g}/\text{day}&lt;/math&gt; for adults.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	The amount of pyrrolizidine alkaloids has to be specified in the given product. The daily exposure has to be below 0.35 $\mu\text{g}$ .

Well-established use	Traditional use
	For more details see the “Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs)” (EMA/HMPC/893108/2011).

## 7. Date of compilation/last revision

5 May 2015