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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Solanum dulcamara* L., stipites

Draft

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End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	15 August 2012
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BG (bългарски): Червено кучешко грозде, стъбло CS (čeština): Potměchuťová větévka DA (dansk): Bittersødstængel DE (Deutsch): Bittersüßstängel EL (elliniká): EN (English): Woody nightshade stem ES (español): Dulcamara, partes aéreas ET (eesti keel): Maavitsa võsud FI (suomi): Punakoiso FR (français): Douce amère (tige de) HU (magyar): Ebszőlő csucsor ág IT (italiano): Dulcamara steli	LT (lietuvių kalba): LV (latviešu valoda): Bebrukārklīņa stumbrs MT (malti): NL (nederlands): Bitterzoet PL (polski): Pęd psianki słodkogórz PT (português): Dulcamara, parte aérea RO (română): SK (slovenčina): Pne ľuľka sladkohorkého SL (slovenščina): Steblo grenkoslada SV (svenska): Besksöta <i>IS (islenska):</i> <i>NO (norsk):</i> Slyngsøtvierstengel
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# Community herbal monograph on *Solanum dulcamara* L., stipites

## 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>Solanum dulcamara</i> L., stipites (woody nightshade stem)</p> <p>i) Herbal substance Not applicable.</p> <p>ii) Herbal preparations Comminuted herbal substance.</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance for infusion or decoction preparation 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 for the relief of symptoms of mild chronic eczema.</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> The herbal substance consists of dried 2 to 3 year old stems of the plant, harvested in spring prior to leaf development or in the late autumn after leaves have dropped.

#### 4.2. Posology and method of administration<sup>3</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adults and elderly</i></p> <p>Comminuted herbal substance for infusion or decoction preparation for cutaneous use: 1-2 g of the comminuted herbal substance in 250 ml of water 1-5 times daily.</p> <p>The infusion/decoction (at room temperature) is applied on the afflicted area with a clean dressing.</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><b>Duration of use</b></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.

#### 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>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

<sup>3</sup> For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

#### **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>
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.  No fertility data available.

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

<b>Well-established use</b>	<b>Traditional use</b>
	No studies on the effect on the ability to drive and use machines have been performed.

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

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

#### **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 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

27 March 2012