



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

15 January 2013  
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Committee on Herbal Medicinal Products (HMPC)

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

Final

|  |                                 |
|--|---------------------------------|
| Discussion in Working Party on Community monographs and Community list (MLWP)          | September 2011<br>November 2011 |
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| <b>Keywords</b> | Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Solanum dulcamara</i> L., stipites; <i>Solani dulcamarae stipites</i> ; woody nightshade stem |
|-----------------|---|

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|---|---|
| BG (bългарски): Червено кучешко грозде, стъбло<br>CS (čeština): Potměchuťová větévka<br>DA (dansk): Bittersødstængel<br>DE (Deutsch): Bittersüßstängel<br>EL (elliniká): Στρώχνου του γλυκúπικρου βλαστοί<br>EN (English): woody nightshade stem<br>ES (español): Dulcamara, partes aéreas<br>ET (eesti keel): Maavitsa võsud<br>FI (suomi): Punakoiso<br>FR (français): Douce amère (tige de)<br>HU (magyar): Ebszóló csucsor ág<br>IT (italiano): Dulcamara steli | LT (lietuvių kalba): Karklavių stiebai<br>LV (latviešu valoda): Bebrukārklīņa stumbrs<br>MT (malti):<br>NL (nederlands): Bitterzoet<br>PL (polski): Pełd psianki słodkogórz<br>PT (português): Dulcamara, parte aérea<br>RO (română):<br>SK (slovenčina): Vetvičky ľuľka sladkohorkého<br>SL (slovenščina): Steblo grenkoslada<br>SV (svenska): Besksöta, stjälk<br><i>IS (íslenska):</i><br><i>NO (norsk):</i> Slyngsøtvierstengel |
|---|---|



# 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<br/>Not applicable.</p> <p>ii) Herbal preparations<br/>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 symptomatic relief of mild recurrent 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 years 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:<br/>1-2 g of the comminuted herbal substance in 250 ml of water 1-5 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><b>Duration of use</b></p> <p>If the symptoms persist longer than 2 weeks 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> <p>The infusion/decoction (at room temperature) is applied on the afflicted area with a clean dressing.</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.<br><br>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.<br><br>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.<br><br>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

15 January 2013