



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Sideritis scardica* Griseb.; *Sideritis clandestina* (Bory & Chaub.) Hayek; *Sideritis raeseri* Boiss. & Heldr.; *Sideritis syriaca* L., herba  
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>	31 October 2015
Rediscussion in MLWP	
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BG (bulgarski): Мурсалски чай, стрък CS (čeština): nař hojnřku DA (dansk): Kortkroneurt DE (Deutsch): Berufskraut EL (elliniká): Πόα σιδηρίτου EN (English): Ironwort ES (español): Siderita, partes aéreas de ET (eesti keel): haavarohuürt FI (suomi): raudakki, verso FR (français): Crapaudine (parties aériennes de) HR (hrvatski): očistova zelen HU (magyar): Sármányvirág virágos hajtása IT (italiano): Stregonia parti aeree fiorite	LT (lietuvių kalba): Timsrų žolė LV (latviešu valoda): Siderītu laksts MT (Malti): ħaxixa tas-Sideritis NL (Nederlands): (Griekse) bergthee, kruid PL (polski): Ziele gojnika PT (português): Siderite, partes aéreas RO (română): SK (slovenčina): Vňař ránhoja SL (slovenščina): zel sklepnjaka SV (svenska): Sårmynta, ört IS (íslenska): NO (norsk): Gresk fjellte
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**European Union herbal monograph on *Sideritis scardica* Griseb.; *Sideritis clandestina* (Bory & Chaub) Hayek, *Sideritis raeseri* Boiss & Heldr., *Sideritis syriaca* L., herba**

## 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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended  <i>Sideritis scardica</i> Griseb.; <i>Sideritis clandestina</i> (Bory & Chaub) Hayek, <i>Sideritis raeseri</i> Boiss & Heldr., <i>Sideritis syriaca</i> L., herba (Ironwort)  i) Herbal substance  Not applicable.  ii) Herbal preparations  Comminuted herbal substance

## 3. Pharmaceutical form

Well-established use	Traditional use
.	Comminuted herbal substance as herbal tea for oral use.  The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1)  Traditional herbal medicinal product used for the

<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 specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State

Well-established use	Traditional use
	<p>relief of cough associated with cold.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product used for the relief of mild gastrointestinal discomfort.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

## 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>Indication 1) and 2)</p> <p>Single dose</p> <p>Herbal tea: 2-4 g of the comminuted herbal substance in 150-200 ml of water as a herbal infusion 2-3 times daily</p> <p>Daily dose up to 12 g</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>Indication 1)</p> <p>If the symptoms persist longer than 1 week, during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 2)</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>Oral use.</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).

### 4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance and to other plants of the Lamiaceae (Labiatae) family.

### 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>

### 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
	<p>Safety during pregnancy and lactation has not been established. 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

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

### 4.8. Undesirable effects

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

## 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>Four <i>Sideritis scardica</i> dry extracts of different polarity (water, 20% and 50% V/V ethanol, and n-heptane) were tested (AMES-test in <i>Salmonella typhimurium</i> strains TA 98, TA 100, TA 1535, TA 1537 and TA 102 with and without metabolic activation). No signs of genotoxicity and mutagenicity were observed.</p> <p>Tests on carcinogenicity and reproductive toxicity have not been performed.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

7 July 2015