



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## European Union list entry on *Sideritis scardica* Griseb., 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	
Adoption by HMPC	

<b>Keywords</b>	Herbal medicinal products; HMPC; European Union list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Sideritis scardica</i> Griseb.; Sideritis herba; Ironwort
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## Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products on *Sideritis scardica* Griseb., herba

<b>Scientific name of the plant</b>	
<i>Sideritis scardica</i> Griseb., herba	
<b>Botanical family</b>	
Lamiaceae (Labiatae)	
<b>Herbal substance</b>	
Sideritis herba	
<b>Common name of herbal substance in all EU official languages</b>	
BG (bulgarski): Мурсалски чай, стрък CS (čeština): nař hojnřku DA (dansk): Kortkroneurt DE (Deutsch): Berufskraut EL (elliniká): Πόα σιδηριτου 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): ořistova zelen HU (magyar): Sármányvirág virágos hajtása IT (italiano): Stregonia parti aeree fiorite	LT (lietuvių kalba): Timsruų 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): Vňat ránhoja SL (slovenščina): zel sklepnjaka SV (svenska): Sårmynta, ört <i>IS (íslenska):</i> <i>NO (norsk):</i> Gresk fjellte
<b>Herbal preparations</b>	
Comminuted herbal substance	
<b>European Pharmacopoeia monograph reference</b>	
Not applicable.	
<b>Indication(s)</b>	
Indication 1) Traditional herbal medicinal product used for the relief of cough associated with cold.	
Indication 2) Traditional herbal medicinal product used for the relief of mild gastrointestinal discomfort. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.	
<b>Type of tradition</b>	
European	

<b>Specified strength</b>
Please see 'Specified posology'.
<b>Specified posology</b>
<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 adolescents under 18 years of age is not recommended (see section 'Special warnings and precautions for use').</p>
<b>Route of administration</b>
Oral use.
<b>Duration of use or any restrictions on the duration of use</b>
<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>
<b>Any other information necessary for the safe use</b>
<p><b>Contraindications</b></p> <p>Hypersensitivity to the active substance and to other plants of the Lamiaceae (Labiatae) family.</p> <p><b>Special warnings and precautions for use</b></p> <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> <p><b>Interactions with other medicinal products and other forms of interaction</b></p> <p>None reported.</p> <p><b>Fertility, pregnancy and lactation</b></p> <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>

**Effects on ability to drive and use machines**

No studies on the effect on the ability to drive and use machines have been performed.

**Undesirable effects**

None known.

If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

**Overdose**

No case of overdose has been reported.

**Pharmaceutical particulars [If necessary]**

Not applicable.

**Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [If necessary for the safe use of the product]**

Not applicable.

**Date of compilation/Last revision**

7 July 2015