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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Marrubium vulgare* 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>	15 April 2013
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BG (bългарски): Пчелник, стрък CS (čeština): Jablečnicková nať DA (dansk): Kransburre DE (Deutsch): Andornkraut EL (elliniká): Πόα πρασίου του κοινοῦ EN (English): White Horehound ES (español): Marrubio, sumidad florida de ET (eesti keel): Penimündiürt FI (suomi): Hurtanminttu FR (français): Marrube (parties aériennes de) HU (magyar): Orvosi pemetefű virágos hajtás IT (italiano): Marrubio bianco (parti aeree fiorite)	LT (lietuvių kalba): Šantrų žolė LV (latviešu valoda): Marūbijas laksts MT (malti): Marrubja NL (nederlands): Malrove PL (polski): Ziele szanty PT (português): Marroio branco, parte aérea florida RO (română): Iarbă de unguiaș SK (slovenčina): Jablčnicková vňať SL (slovenščina): Zel navadne črne mete SV (svenska): Kransborre IS (íslenska): . NO (norsk): Borremynte
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# Community herbal monograph on *Marrubium vulgare* 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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Marrubium vulgare</i> L., herba (White Horehound)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Powdered herbal substance</p> <p>c) Expressed juice (DER 1:0.70-0.90)</p> <p>d) Liquid extract (DER 1: 0.9-1.1), extraction solvent ethanol 20-30% V/V</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Herbal preparations in solid or liquid dosage forms for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</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 material complies with the Ph. Eur. monograph (ref.: 01/2008: 1835 corrected 6.0).

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p><b>Indication 1)</b> Traditional herbal medicinal product used as an expectorant in cough associated with cold.</p> <p><b>Indication 2)</b> Traditional herbal medicinal product used for symptomatic treatment of mild dyspeptic complaints such as bloating and flatulence.</p> <p><b>Indication 3)</b> Traditional herbal medicinal product used in temporary loss of appetite.</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>Adolescents over 12 years of age, adults and elderly</i></p> <p>a) Comminuted herbal substance Single dose Herbal tea: 1-2 g of the comminuted herbal substance in 250 ml of boiling water as a herbal infusion 3 times daily. Daily dose: 3-6 g</p> <p>b) Powdered herbal substance Single dose: 225-450 mg 3 times daily Daily dose: 675-1350 mg</p> <p>c) Expressed juice Single dose: 10-20 ml 3 times daily Daily dose: 30-60 ml</p> <p>d) Liquid extract Single dose: 1.5-4 ml 3 times daily Daily dose: 4.5-12 ml</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).

Well-established use	Traditional use
	<p>The use in children under 12 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><b>Indication 1)</b> If the symptoms persist longer than one week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Indications 2) and 3)</b> If the symptoms persist longer than two 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> <p><b>Indications 2) and 3)</b> The herbal preparations should be taken ½ hour before meal.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance and to other plants of the Lamiaceae family.</p> <p>Obstruction of the bile duct, cholangitis, liver disease, ileus.</p>

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Patients with active peptic ulcer, gallstones and any other biliary disorders should consult a doctor before using Marrubii herba preparations.</p> <p>The use in children under 12 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>For extracts containing ethanol, the appropriate</p>

Well-established use	Traditional use
	labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

#### ***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
	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***

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
	None known.  If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

#### ***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
	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

15 January 2013