EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 July 2013
EMA/HMPC/604271/2012
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Marrubium vulgare* L., herba

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	September 2012 November 2012
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	15 January 2013
End of consultation (deadline for comments[1])	15 April 2013
Rediscussion in Working Party on Community monographs and Community list (MLWP)	May 2013
Adoption by Committee on Herbal Medicinal Products (HMPC)	9 July 2013

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Marrubium vulgare* L., herba; Marrubii herba; White Horehound

BG (bălgarski): Пчелник, стрък CS (čeština): Jablečníková nať DA (dansk): Kransburre DE (Deutsch): Andornkraut EL (elliniká): Πόα πρασίου του κοινού EN (English): White Horehound ES (espanol): 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): Marrūbijas laksts MT (malti): Marrubja NL (nederlands): Malrove PL (polski): Ziele szanty PT (português): Marroio branco, parte aérea florida RO (română): Iarbă de unguraş SK (slovenčina): Jablčníková vňať SL (slovenščina): Zel navadne črne mete SV (svenska): Kransborre *IS (íslenska)*: . *NO (norsk)*: Borremynte

[1] No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

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[2, 3]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Marrubium vulgare* L., herba (White Horehound) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Expressed juice (DER 1:0.70-0.90) d) Liquid extract (DER 1:0.9-1.1), extraction solvent ethanol 20-30% V/V

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[2] 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
	Indication 1) Traditional herbal medicinal product used as an expectorant in cough associated with cold. Indication 2) Traditional herbal medicinal product used for symptomatic treatment of mild dyspeptic complaints such as bloating and flatulence. Indication 3) Traditional herbal medicinal product used in temporary loss of appetite. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration[4]

Well-established use	Traditional use
	Posology *Adolescents over 12 years of age, adults and elderly* Indications 1), 2) and 3) 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 b) Powdered herbal substance Single dose: 225-450 mg, 3 times daily Daily dose: 675-1350 mg c) Expressed juice Single dose: 10-20 ml, 3 times daily Daily dose: 30-60 ml d) Liquid extract Single dose: 1.5-4 ml, 3 times daily

[4] 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
	Daily dose: 4.5-12 ml The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) 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. Indications 2) and 3) 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. **Method of administration** Oral use. Indications 2) and 3) The herbal preparations should be taken ½ hour before meal.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance and to other plants of the Lamiaceae (Labiatae) family. Obstruction of the bile duct, cholangitis, liver disease, ileus.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Patients with active peptic ulcer, gallstones and any other biliary disorders should consult a doctor before using Marrubii herba preparations. The use in children under 12 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health

Well-established use	Traditional use
	care practitioner should be consulted. For extracts containing ethanol, the appropriate 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

9 July 2013