2 February 2016
EMA/HMPC/46758/2015
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Pistacia lentiscus* L., resina (mastic)

Final

Discussion in Working Party on European Union monographs and list (MLWP)	November 2014 January 2015 March 2105 May 2015
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	07 July 2015
End of consultation (deadline for comments)[1]	31 October 2015
Re-discussion in MLWP	25 November 2015
Adoption by HMPC	02 February 2016

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Pistacia lentiscus* L., resina, Mastix, Mastic tree resin

BG (bulgarski): Мастикс CS (čeština): list/pryskyřice pistácie lentišku DA (dansk): Mastiks DE (Deutsch): Mastix EL (elliniká): Ρητίνη Μαστίχης Χίου EN (English): Mastic tree resin ES (español): Lentisco, resina de ET (eesti keel): mastiks FI (suomi): mastiksipistaasi, hartsi FR (français): Mastic HR (hrvatski): Mastiks HU (magyar): pisztáciagyanta IT (italiano): lentisco resina	LT (lietuvių kalba): mastikà LV (latviešu valoda): Mastikas pistācijas sveķi MT (Malti): reżina tad-Deru NL (Nederlands): Mastiekboom, hars (mastiek) PL (polski): Mastyks PT (português): Mastique RO (română): Mastic SK (slovenčina): Mastix SL (slovenščina): mastiks SV (svenska): Mastix IS (íslenska): NO (norsk): Mastiks

[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'.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

European Union herbal monograph on *Pistacia lentiscus* L., resina (mastic)

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 *Pistacia lentiscus* L., resina (mastic) i) Herbal substance Not applicable ii) Herbal preparations Powdered herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Powdered herbal substance in solid dosage form for oral use. Powdered herbal substance in semi-solid dosage form for cutaneous 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 in mild dyspeptic disorders. Indication 2) Traditional herbal medicinal product used for the

[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

[3] The material complies with the Ph. Eur. monograph (ref.: 1876)

Well-established use	Traditional use
	symptomatic treatment of minor inflammations of the skin and as an aid in healing of minor wounds. The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology Indication 1) *Adults and elderly* Single dose: 0.5-1 g 2 times daily Daily dose: 1-2 g The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication 2) *Adolescents, adults and elderly* Semi-solid preparations containing 9-11% of the powdered herbal substance to be applied as a thin layer on the affected area up to 3 times daily. 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 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 2) 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.

Well-established use	Traditional use
	Method of administration Indication 1) Oral use Indication 2) Cutaneous use

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
	Indication 1) The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Indication 2) The use in children under 12 years of age has not been established due to lack of adequate data. If signs of skin infection are observed, a doctor or a qualified health care practitioner should be consulted. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

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
	No fertility data available. Safety during pregnancy and lactation has not

Well-established use	Traditional use
	been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

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.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the

Well-established use	Traditional use
	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

2 February 2016