



7 July 2015
EMA/HMPC/46758/2015
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Pistacia lentiscus* L., resin (mastix)

Draft

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
Start of public consultation	22 July 2015
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	31 October 2015
Re-discussion in MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Pistacia lentiscus</i> L., resin, Mastix, Mastic tree resin
-----------------	--

BG (bulgarski): Мастикс CS (čeština): list/pryskyřice pistácie lentišku DA (dansk): Mastiks DE (Deutsch): Mastix EL (elliniká): Ρητινή 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): SK (slovenčina): Mastix SL (slovenščina): mastiks SV (svenska): Mastix <i>IS (íslenska):</i> <i>NO (norsk):</i> Mastiks
---	---



European Union herbal monograph on *Pistacia lentiscus* L., resin (mastix)

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{1, 2}

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Pistacia lentiscus</i> L., resin (mastix) 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.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product used in mild dyspeptic disorders.

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.: 1876)

Well-established use	Traditional use
	<p data-bbox="810 255 967 286">Indication 2)</p> <p data-bbox="810 311 1426 416">Traditional herbal medicinal product used for the symptomatic treatment of minor inflammations of the skin and as an aid in healing of minor wounds.</p> <p data-bbox="810 441 1350 546">The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
	<p data-bbox="810 732 935 763">Posology</p> <p data-bbox="810 788 967 819">Indication 1)</p> <p data-bbox="810 844 1031 875"><i>Adults and elderly</i></p> <p data-bbox="810 900 1098 931">Single dose: 0.35-0.5 g</p> <p data-bbox="810 938 1139 969">Daily dose: 3-4 times daily</p> <p data-bbox="810 994 1426 1099">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 data-bbox="810 1124 967 1155">Indication 2)</p> <p data-bbox="810 1180 1190 1211"><i>Adolescents, adults and elderly</i></p> <p data-bbox="810 1236 1426 1341">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.</p> <p data-bbox="810 1366 1410 1471">The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 1496 1015 1527">Duration of use</p> <p data-bbox="810 1552 967 1583">Indication 1)</p> <p data-bbox="810 1608 1410 1749">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 data-bbox="810 1774 967 1805">Indication 2)</p> <p data-bbox="810 1830 1410 1971">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>

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.

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.

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

7 July 2015