



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 July 2013
EMA/HMPC/346737/2011
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Juglans regia* L., folium

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2011 March 2012 May 2012 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
Redisussion 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; <i>Juglans regia</i> L., folium; Juglandis folium; Walnut Leaf
-----------------	-----------------------------------------------------------------------------------------------------------------------------------------------

BG (bългарски): Орех, лист CS (čeština): Ořešákový list DA (dansk): Valnødblad DE (Deutsch): Walnussblätter EL (elliniká): Καρύδας φύλλο EN (English): Walnut Leaf ES (español): Nogal, hoja de ET (eesti keel): Pähklipuuleht FI (suomi): Saksanpähkinä, lehti FR (français): Noyer (feuille de) HR (hrvatska): orahov list HU (magyar): Diólevél IT (italiano): Noce foglia	LT (lietuvių kalba): Graikinių riešutmedžių lapai LV (latviešu valoda): Valrieksta lapas MT (malti): Ġewż NL (nederlands): Walnoot, Okkernoot PL (polski): Liść orzecha włoskiego PT (português): Nogueira, folha RO (română): Frunză de nuc SK (slovenčina): Orechový list SL (slovenščina): List navadnega oreha SV (svenska): Valnötsblad IS (íslenska): NO (norsk): Valnøttblad
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

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'.



Community herbal monograph on *Juglans regia* L., folium

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition²

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>Juglans regia</i> L., folium, (walnut leaf)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparations Comminuted herbal substance</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance for decoction preparation for cutaneous use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product for the relief of minor inflammatory conditions of the skin.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product used in excessive perspiration of hands and feet.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

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

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>Indication 1)</p> <p>Comminuted herbal substance for decoction preparation for cutaneous use: 4-6 g of the comminuted herbal substance in 200 ml of boiling water.</p> <p>Apply as a impregnated dressing to the affected areas of the skin 2 - 4 times daily.</p> <p>Indication 2)</p> <p>Comminuted herbal substance for decoction preparation for cutaneous use: 4-6 g of the comminuted herbal substance in 200 ml of boiling water.</p> <p>Apply as a impregnated dressing to the affected areas of the skin up to 30 minutes twice daily.</p> <p>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>Duration of use</p> <p>Not to be used for more than 1 week.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Cutaneous use.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance.</p> <p>Open wounds and large skin injuries.</p>

³ 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).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use temporarily stains the skin.</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>

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
	<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>

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

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. Adequate 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