



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Aesculus hippocastanum* L., cortex (EMA/HMPC/354156/2011)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Aesculus hippocastanum* L., cortex as released for public consultation on 26 October 2011 until 15 February 2012.

	Organisations and/or individuals
1	European botanical forum (EBF), Brussels, Belgium
2	AESGP, Brussels, Belgium



Table 2: Discussion of comments

GENERAL COMMENTS			
Interested party	Comment and Rationale		Outcome

SPECIFIC COMMENTS ON TEXT			
Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition ¹	EBF	Aesculus hippocastanum L., cortex (horse chestnut bark) ii) Herbal preparation Powdered herbal substance We propose to include Dry extract prepared with water DER: 5-6:1 as mentioned in the assessment report on Aesculus hippocastanum L., cortex, EMA/HMPC/354157/2011, page 4	Not endorsed. As it is mentioned in the assessment report, it has not been proved that this extract has been on the market for 30 years.
	AESGP	Comments: Preparations of Aesculus hippocastanum have also been used for external treatment in the two indications described. These preparations have been on the market within the EU since 1978. The preparation is a tincture manufactured from the bark of <i>Aesculus hippocastanum</i> L. (ratio of herbal substance to extraction solvent 1:8-11), ethanol. decoction, (extraction solvent: ethanol 30 % <i>m/m</i>). This preparation is intended for cutaneous and anorectal use in a liquid or semi-solid (5-10% in cream or gel) dosage form. Proposed change: <u>Insertion of the herbal preparation:</u> "liquid extract of <i>Aesculus hippocastanum</i> L. cortex (1:8-11), ethanol. decoct, extraction solvent ethanol 30 % <i>m/m</i> ."	Not endorsed. No data have been provided to prove the use of these preparations as herbal medicinal product (with therapeutic indication, posology...). Moreover, the method of preparation mentioned in the Weleda Nomenclature clearly refers to the German Homeopathic Pharmacopoeia.

SPECIFIC COMMENTS ON TEXT			
3. Pharmaceutical form	EBF	<p><i>Traditional use</i> <i>"The pharmaceutical form should be described by the European Pharmacopoeia full standard term."</i> Remark: There is no existing monograph for <i>Aesculus hippocastanum</i> L. cortex in EP, neither in National Pharmacopoeias.</p>	This section does not refer to an individual herbal monograph but to the pharmaceutical form of the medicinal product.
	AESGP	<p><u>Insertion of the pharmaceutical form:</u> Herbal preparation: tincture or liquid extracts (DER 1:8-11, ethanol. decoct, extraction solvent ethanol 30 % <i>m/m</i>) for cutaneous and anorectal use.</p>	Not endorsed. See above.
4.2 Posology and method of administration	AESGP	<p><u>Insertion of the posology:</u> Tincture or liquid extracts (DER 1:8-11, ethanol. decoct, extraction solvent ethanol 30 % <i>m/m</i>) in a strength corresponding to 5-10% in semisolid and liquid preparations, several times daily.</p>	Not endorsed. See above.
		<p>Comments: Adolescents over 12 years of age can also suffer from haemorrhoids because of the bad alimentary habits and sedentary lifestyle. So therefore, if adolescents over 12 years of age suffer from haemorrhoids and at some time they have been previously diagnosed by a doctor, after, this diagnosis let them easily recognize the symptoms at first, and then, use <i>Aesculus hippocastanum</i> L. to treat them. Moreover, for the dosage, should be taken into account the corporal volume (weight/height) and not the legal age.</p> <p>Proposed change:</p> <p>Posology for the indication 2 (Traditional herbal medicinal product for symptomatic relief of itching and burning</p>	<p>Not endorsed. No specific data on the use of <i>Aesculus hippocastanum</i> L., cortex and no data on any use of herbal medicinal products used with this indication in this target population have been provided. In the monograph on <i>Ruscus aculeatus</i> L., rhizoma, the indication has been considered as not relevant for children and adolescents.</p>

SPECIFIC COMMENTS ON TEXT			
		<p>associated with haemorrhoids):</p> <p><u>Adults:</u></p> <p>Single dose: 275 mg, 3 to 6 times daily.</p> <p><u>Adolescents over 12 years of age:</u></p> <p><u>Single dose: 275 mg, 3 to 6 times daily as long as there have been in any moment a medical diagnosis.</u></p>	
4.4 Special warnings and precautions for use	AESGP	<p>Comments:</p> <p>Regarding indication 2, it is necessary to clarify that rectal bleeding does not occur as a result of the product intake; it is a normal symptom in haemorrhoids, as long as the blood is red and bright. If the blood is darker, with mucus, etc., it could indicate a more serious pathology; therefore in this case, a doctor should be consulted.</p> <p>Proposed change:</p> <p><u>Warnings and precautions for indication 2):</u> The use in adolescents under 12 years of age has not been established.</p> <p>If there is rectal bleeding with dark blood, with mucus, etc., a doctor should be consulted.</p>	The wording of this section is in line with the wording of other traditional herbal medicinal products which have the same indication.
<p>References:</p> <p>[1] Weleda Arzneimittelverzeichnis 1978</p> <p>[2] Weleda Vademécum 1992</p> <p>[3] Weleda Nomenclature 1989</p> <p>[4] Guía de práctica clínica sobre el manejo del paciente con rectorragia P. Alonso^a, M. Marzo^a, J.J. Mascort^b, A. Hervás^c, L. Viñas^b, J. Ferrús^b, J. Ferrándiz^b, L. López-Rivas^c, X. Bonfill^a y J.M. Piqué^c. Gastroenterol Hepatol 2002; 25(10):605-32.</p> <p>[5] Problemas gastrointestinales y médicos en la mujer: Hemorroides. Guía de Salud para el consumidor. Colegio Americano de Gastroenterología.</p> <p>[6] [MedlinePlus] «Hemorroides». Enciclopedia médica en español. Actualizado el 13 de diciembre de 2011.</p> <p>[7] National Digestive Diseases Information Clearinghouse (NDDIC). Haemorrhoids.</p>			