



London, 14 January 2010
Doc. Ref. EMA/HMPC/5816/2010

**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

**COMMUNITY LIST ENTRY ON
VITIS VINIFERA VAR. *TINCTORIA* L., FOLIUM**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	January 2010
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	14 January 2010
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 May 2010
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Vitis vinifera</i> var. <i>tinctoria</i> L.; <i>Vitis viniferae</i> folium; red vine leaf
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**ENTRY TO LIST OF HERBAL SUBSTANCES, PREPARATIONS AND
COMBINATIONS THEREOF FOR USE IN
TRADITIONAL HERBAL MEDICINAL PRODUCTS**

**ENTRY TO LIST OF HERBAL SUBSTANCES, PREPARATIONS AND
COMBINATIONS THEREOF FOR USE IN
TRADITIONAL HERBAL MEDICINAL PRODUCTS:
VITIS VINIFERA VAR. TINCTORIA L., FOLIUM**

Scientific name of the plant	
<i>Vitis vinifera</i> var. <i>tinctoria</i> L.; folium	
Botanical family	
Vitaceae	
Herbal substance	
Red vine leaf	
Common name in all EU official languages of herbal substance	
BG (bългарski): CS (čeština): DA (dansk): DE (Deutsch): Rebe Blatter EL (elliniká): Φύλλο Αμπέλου EN (English): ES (español): Hojas de vid roja ET (eesti keel): FI (suomi): FR (français): Feuilles de vigne HU (magyar): IT (italiano): Fogli della vite	LT (lietuvių kalba): LV (latviešu valoda): MT (malti): NL (nederlands): Wijnstok bladeren PL (polski): liść winorośli właściwej PT (português): Folhas da videira RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): IS (íslenska): NO (norsk):
Herbal preparation(s)	
Soft extract (DER 4-6:1; extraction solvent water)	
European Pharmacopoeia monograph reference	
Not applicable.	
Indication(s)	
Traditional herbal medicinal product to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.	
Type of tradition	
European	

Specified strength
See ‘Specified posology’.
Specified posology
<p><i>Adults and elderly</i></p> <p>Soft extract in a cream base (10 g contain 282 mg soft extract)</p> <p>Apply a thin layer on the affected area 1-3 times a day.</p> <p>The use is not recommended in children and adolescents under 18 years of age (see ‘Special warnings and precautions for use’).</p>
Route of administration
Cutaneous use.
Duration of use or any restrictions on the duration of use
If the symptoms persist for more than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.
Any other information necessary for the safe use
<p>Contraindications Hypersensitivity to the active substance.</p> <p>Special warnings and precautions for use If there is inflammation of the skin, thrombophlebitis or subcutaneous induration, severe pain, ulcers, sudden swelling of one or both legs, cardiac or renal insufficiency, a doctor should be consulted.</p> <p>The product should not be used on broken skin, around the eyes or on mucous membranes.</p> <p>The use in children under 18 years of age is not recommended due to the lack of adequate data.</p> <p>Interactions with other medicinal products and other forms of interaction None reported.</p> <p>Pregnancy and lactation Safety during pregnancy and lactation has not been established.</p> <p>In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>Effects on ability to drive and use machines No studies on the effect on the ability to drive and use machines have been performed.</p>

Undesirable effects

Contact allergy and/or hypersensitivity reactions of the skin (itching and erythema, urticaria) have been reported. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

Overdose

No case of overdose has been reported.

Pharmaceutical particulars [If necessary]

Not applicable.

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [If necessary for the safe use of the product]

Not applicable.

Date of compilation/Last revision

14 January 2010