



European Medicines Agency  
Evaluation of Medicines for Human Use

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

**FINAL**

**COMMUNITY HERBAL MONOGRAPH ON  
*VERBASCUM THAPSUS* L., *V. DENSIFLORUM* BERTOL. AND *V. PHLOMOIDES* L., FLOS**

<b>DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	September 2007 October 2007
<b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>	31 October 2007
<b>END OF CONSULTATION (DEADLINE FOR COMMENTS)</b>	15 February 2008
<b>REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	March 2008 July 2008
<b>ADOPTION BY HMPC</b>	3 July 2008

**KEYWORDS**

Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Verbascum thapsus* L.; *V. densiflorum* Bertol.; *V. phlomoides* L.; Verbasci flos; mullein flower

**COMMUNITY HERBAL MONOGRAPH ON *VERBASCUM THAPSUS* L.,  
*V. DENSIFLORUM* BERTOL. AND *V. PHLOMOIDES* L., FLOS**

**1. NAME OF THE MEDICINAL PRODUCT**

To be specified for the individual finished product.

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION<sup>1, 2</sup>**

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Verbascum thapsus</i> L., <i>V. densiflorum</i> Bertol. (<i>V. thapsiforme</i> Schrad), and <i>V. phlomoides</i> L., flos (mullein flower)</p> <p>i) Herbal substance Dried flowers, reduced to the corolla and the androecium</p> <p>ii) Herbal preparations Comminuted herbal substance</p>

**3. PHARMACEUTICAL FORM**

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Herbal substance or herbal preparation as herbal tea for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

<sup>1</sup> The material complies with the Ph. Eur. monograph (ref. 01/2008:1853 corrected 6.0).

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

#### 4. CLINICAL PARTICULARS

##### 4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u>  Herbal medicinal product traditionally used to relieve symptoms of sore throat associated with dry cough and cold.  The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.
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##### 4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u>  <b>Posology</b>  <i>Adolescents over 12 years of age, adults, elderly</i>  Herbal substance or herbal preparation for tea preparation: approximately 1.5 - 2 g, 3-4 times daily.  The use is not recommended in children under 12 years of age (see section 4.4 Special warnings and precautions for use).  <b>Duration of use</b>  Not to be taken for more than 1 week.  If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.  <b>Method of administration</b>  Oral use.
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##### 4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u>  Hypersensitivity to the active substance .
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#### 4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u>
	<p>The use is not recommended in children under 12 years of age due to lack of adequate data.</p> <p>When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.</p>

#### 4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u>
	<p>None reported.</p>

#### 4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u>
	<p>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>

#### 4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u>
	<p>No studies on the effect on the ability to drive and use machines have been performed.</p>

#### 4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u>
	<p>None known.</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

#### 4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u>
	<p>No case of overdose has been reported.</p>

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

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

### 5.2. Pharmacokinetic properties

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

### 5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	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

<u>Well-established use</u>	<u>Traditional use</u>
	Not applicable.

## 7. DATE OF COMPILATION/LAST REVISION

3 July 2008