



27 March 2018  
EMA/HMPC/611537/2016  
Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Verbascum thapsus* L., *V. densiflorum* Bertol. (*V. thapsiforme* Schrad) and *V. phlomoides* L., flos

Final

<b>Initial assessment</b>	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	September 2007 October 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	31 October 2007
End of consultation (deadline for comments)	15 February 2007
Rediscussion in MLWP	March 2008 July 2008
Adoption by HMPC	3 July 2008
<b>First systematic review</b>	
Discussion in MLWP	September 2016 November 2016 January 2017 March 2017 May 2017 November 2017 January 2018
Adoption by HMPC	27 March 2018
Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Verbascum thapsus</i> L.; <i>V. densiflorum</i> Bertol.; <i>V. phlomoides</i> L.; Verbasci flos; mullein flower



BG (bulgarski): Лопен, цвят	LT (lietuvių kalba): Tūbių žiedai
CS (čeština): diviznový květ	LV (latviešu valoda): Deviņvīru spēka ziedi
DA (dansk): Kongelysblomst	MT (Malti): fjura tax-xatbet I-andar
DE (Deutsch): Wollblumen	NL (Nederlands): Koningskaars, Stalkaars, Keizerskaars
EL (elliniká): ανθός φλόμου	PL (polski): Kwiat dziewanny
EN (English): mullein flower	PT (português): verbasco, flor
ES (español): gordolobo, flor de	RO (română): floare de lumânărică
ET (eesti keel): vägiheinaõis	SK (slovenčina): kvet divozela
FI (suomi): tulikukka, kukka (ukontulikukka)	SL (slovenščina): cvet lučnika
FR (français): bouillon blanc (fleur de)	SV (svenska): Kungsljus, blomma
HR (hrvatski): divizmin cvijet	IS (íslenska):
HU (magyar): ökörfarkkoró virágpárta	NO (norsk): filtkongelysblomst
IT (italiano): Verbasco fiore	

# European Union herbal monograph on *Verbascum thapsus* L., *V. densiflorum* Bertol. (*V. thapsiforme* Schrad), 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>

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC.</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</p> <p>As defined in the Ph. Eur. monograph.</p> <p>ii) Herbal preparations</p> <p>Comminuted herbal substance.</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal substance or comminuted herbal substance as herbal tea for oral 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>Traditional herbal medicinal product used to relieve symptoms of sore throat associated with dry cough and cold.</p>

<sup>1</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

<sup>2</sup> The material complies with the Ph. Eur. Monograph (ref.: 1853).

Well-established use	Traditional use
	The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

#### 4.2. Posology and method of administration<sup>3</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose:</p> <p>Herbal tea: 1.5-2 g of the herbal substance or the comminuted herbal substance in 150 ml boiling water as a herbal infusion three to four times daily.</p> <p>Daily dose: 4.5-8 g</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Duration of use</b></p> <p>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> <p><b>Method of administration</b></p> <p>Oral use</p>

#### 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
	<p>The use in children under 12 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>

<sup>3</sup> 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)

Well-established use	Traditional use
	If dyspnoea, fever or purulent sputum occurs, 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
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.  No fertility data available.

#### **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.

### 5.2. Pharmacokinetic properties

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

### 5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, 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

27 March 2018