



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Zea mays* L., stigma

Draft

Initial assessment	
Discussion in Committee on Herbal Medicinal Products (HMPC)	March 2024 May 2024 July 2024 November 2024 January 2025 March 2025 May 2025 July 2025 September 2025
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BG (bulgarski): Царевична коса	LT (lietuvių kalba): Kukurūzų purkos
CS (čeština): kukuřičná blizna	LV (latviešu valoda): Kukurūzas drīksna
DA (dansk): Majssilke	MT (Malti): qamħirrun
DE (Deutsch): Maisgriffel	NL (Nederlands): Maïszijde
EL (elliniká): Αραβοσίτου στίγμα	PL (polski): znamiona kukurydzy
EN (English): Corn silk	PT (português): Milho, estigmas
ES (español): maíz, estigmas de	RO (română): mătasea de porumb
ET (eesti keel):	SK (slovenčina): blizna kukurice
FI (suomi): maissi, emin luotti (maissisilkki)	SL (slovenščina): koruzni laski
FR (français): maïs (pistil de)	SV (svenska): majs, pistillmärke (majssilke)
HR (hrvatski): kukuruzna svila	IS (íslenska):
HU (magyar): Kukoricakeményítő	NO (norsk): Maishår/silke
IT (italiano): Mais, stigma	

European Union herbal monograph on *Zea mays* L., stigma

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{1, 2}

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC <i>Zea mays</i> L., stigma (Maydis stigma) i) Herbal substance Not applicable. ii) Herbal preparations Comminuted herbal substance.

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine.

¹ The declaration of the active substance for an individual finished product should be in accordance with relevant herbal quality guidance.

² The material complies with the National Romanian Pharmacopoeia (Farmacopea Romana Ed A X-A, 1998) in use officially in Romania.

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 administration³

Well-established use	Traditional use
	Posology <i>Adolescents, Adults and Elderly</i> Herbal tea, decoction: 2 – 4 g of comminuted herbal substance in 200 ml of boiling water as a decoction (boiled for 5 minutes) 2 - 3 times daily. Daily dose 4 g –12 g Herbal tea, infusion: 4 – 8 g of comminuted herbal substance in 200 ml of boiling water as a herbal infusion 3 times daily, corresponding to the daily doses 12 g - 24 g. Daily dose 12 g – 24.0 g. The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Duration of use If the symptoms persist longer than 2 weeks during the use of the medicinal product a doctor or a qualified health care practitioner should be consulted. Method of administration Oral use. Decoctions to be taken between meals.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

³ General rules for preparing infusions and decoctions/macerate are given in HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children under 12 years of age has not been established due to lack of adequate data. If urinary tract complaints worsen and symptoms such as fever, dysuria, spasm, or blood in the urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Because adequate fluid intake is required during treatment, it is not recommended for patients with conditions where reduced fluid intake is advised.

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.

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. Tests on reproductive toxicity, and genotoxicity have not been performed. Tests on carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

24 September 2025