29 May 2024  
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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Tribulus terrestris* L., herba  
Draft

<table>
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<th>Initial assessment</th>
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| Discussion in Committee on Herbal Medicinal Products (HMPC)                       | May 2022  
November 2022  
January 2023  
July 2023  
September 2023  
March 2024  
May 2024 |
| Adopted by HMPC for release for consultation                                      | 29 May 2024 |
| Start of public consultation                                                     | 15 June 2024 |
| End of consultation (deadline for comments). Comments should be provided using this template. The completed comments form should be sent to hmpc.secretariat@ema.europa.eu | 15 September 2024 |

**Keywords**  
Herbal medicinal products; HMPC; European Union herbal monographs;  
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Tribuli terrestris herba, puncture vine herb/caltrop herb
Public statement on *Tribulus terrestris* L., herba

**PROBLEM STATEMENT**

The HMPC decided to prepare a European Union herbal monograph on *Tribulus terrestris* L., herba as announced in the May 2021 HMPC meeting report.

The herbal substance consists of dried, whole, or fragmented flowering and fruit bearing aerial parts of *Tribulus terrestris* L.

A comprehensive literature search was conducted and available data, including information on products on the market in the European Union (EU), were assessed in relation to the requirements laid down in Directive 2001/83/EC and its Annex I, in particular Article 10a and Chapter 2a.

The only preparation on the EU market derived from *Tribulus terrestris* L., herba is a dry extract (DER 35-45:1), extraction solvent methanol 80% V/V, containing not less than 45% of furostanol saponins calculated as protodioscin, approved in Bulgaria since 1981.

Although a period of 10 years medicinal use of the product has elapsed, data supporting an acceptable level of safety and a recognized efficacy are not available as published data.

Although the requirement of 30 years on the market is fulfilled, the extract is considered specific and therefore not appropriate to support the establishing of a EU herbal monograph based on traditional use. Sufficient information on traditional use of other *Tribulus terrestris* L., herba preparations has not been found in the searched literature.

Altogether, a European Union herbal monograph based on traditional use and/or well-established use cannot be established at present.

The HMPC is fully aware that there may be non-authorised/non-registered products with *Tribulus terrestris* on the EU market, however, these products may not be sufficiently characterised, and information about a long-standing safe medicinal use according to a specific indication, strength and posology is considered insufficient. This also includes the use of *Tribulus terrestris* based on a non-European tradition.

The HMPC concluded that the following requirements for the establishment of a European Union herbal monograph on traditional and/or well-established herbal medicinal products containing *Tribulus terrestris* L., herba are not fulfilled:

- the requirement laid down in Article 10a of Directive 2001/83/EC that the active substance has a recognised efficacy and an acceptable level of safety and that the period of well-established medicinal use has elapsed;

- the requirement laid down in Article 16a(1)(d) of Directive 2001/83/EC that “the period of traditional use as laid down on Article 16c(1)(c) has elapsed”.

**CONCLUSIONS**

Based on the above-mentioned information, the HMPC is of the opinion that a European Union herbal monograph on *Tribulus terrestris* L., herba cannot be established unless additional information will be submitted during the period of public consultation.

The HMPC will welcome the provision of the necessary data to allow continuation of the assessment work.
To read more about the assessment carried out, a link is provided to the page where to access the draft assessment report on *Tribulus terrestris* L., herba and its list of references.