



04 March 2026
EMA/HMPC/139333/2025
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Ruscus aculeatus* L., rhizoma

Rapporteur(s)	H. Kuin
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HMPC decision on review of monograph <i>Ruscus aculeatus</i> L., rhizoma adopted on 20 November 2018	31 January 2024
Call for scientific data (start and end date)	From 01 March 2024 to 31 May 2024
Discussion in HMPC	May 2025 July 2025 September 2025 November 2025 January 2026 March 2026
Adoption by HMPC	04 March 2026

Review of new data Periodic review (from 2017 to 2025)

Sources checked for new information:

Scientific data (e.g. non-clinical and clinical safety data, clinical efficacy data)

- Scientific/Medical/Toxicological databases
- Pharmacovigilance databases
 - data from EudraVigilance
 - from other sources (e.g. data from VigiBase, national databases)
- Other



Regulatory practice

- Old market overview in AR (i.e. check products fulfilling 30/15 years of TU or 10 years of WEU on the market)
- New market overview (including pharmacovigilance actions taken in member states)
- PSUSA
- Feedback from experiences with the monograph during MRP/DCP procedures
- Ph. Eur. monograph
- Other data submitted by interested parties
- Consistency (e.g. scientific decisions taken by HMPC)
 - Public statements or other decisions taken by HMPC
 - Consistency with other monographs within the therapeutic area
 - Other

Availability of new information that could trigger a revision of the monograph

<i>Scientific data</i>	Yes	No
New non-clinical safety data that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New clinical safety data that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New data introducing a possibility of a new list entry	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New clinical data regarding the paediatric population or the use during pregnancy and lactation that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New clinical studies introducing a possibility for new WEU indication/preparation	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other scientific data that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Regulatory practice</i>	Yes	No
New herbal substances/preparations with 30/15 years of TU	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New herbal substances/preparations with 10 years of WEU	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New recommendations from a finalised PSUSA	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Feedback from experiences with the monograph during MRP/DCP procedures that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New/Updated Ph. Eur. monograph that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other regulatory practices that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Consistency</i>	Yes	No
New or revised public statements or other HMPC decisions that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Relevant inconsistencies with other monographs within the therapeutic area that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other relevant inconsistencies that could trigger a revision of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Summary of new references

PubMed was searched on 11-04-2025 with search terms [Ruscus aculeatus] OR [Ruscus] between 2017-2025 and 35 references were retrieved. Most are reviews that do not add new information to the assessment report or EU herbal monograph.

Assessment of new data

New scientific data that could trigger a revision of the monograph

Eudravigilance was searched on 14-04-2025 using the term [Ruscus aculeatus]. The reported adverse event was rectal bleeding (1). Vigibase was searched on 06-04-2025. The reported adverse events were skin rash (4), rectal bleeding (1), pruritus (2), urticaria (1), oedema (1), diarrhoea (1) and colitis (1).

Assessor's comment:

The reported adverse events do not trigger a revision of the EU herbal monograph.

New regulatory practice that could trigger a revision of the monograph

There have been no new authorised/registered preparations containing Ruscus aculeatus root as a single herbal substance/preparation reported since 2017.

The dried herbal substance registered in Austria since 2013 as a traditional herbal medicinal product according to Article 16a of the Directive has been withdrawn since 2021.

Assessor's comment:

No new herbal medicinal products with the herbal substance/herbal preparations of Ruscus aculeatus root as the sole active substance have been registered/authorised since the last revision in 2017. One product containing dried powdered Ruscus aculeatus root has been withdrawn in Austria. However, this has no consequence for the EU herbal monograph.

Inconsistency that could trigger a revision of the monograph

No inconsistency has been found.

Other issues that could trigger a revision of the monograph

Not applicable.

New information not considered to trigger a revision at present but that could be relevant for the next review

Not applicable.

References

Not applicable.

Rapporteur's proposal on revision

Revision needed, i.e. new data/findings of relevance for the content of the monograph:

Revision likely to have an impact on the corresponding list entry (if applicable)

No revision needed, i.e. no new data/findings of relevance for the content of the monograph

HMPC decision on revision

Revision needed, i.e. new data/findings of relevance for the content of the monograph

No revision needed, i.e. no new data/findings of relevance for the content of the monograph