



22 September 2021
EMA/HMPC/637909/2018
Committee on Herbal Medicinal Products (HMPC)

Addendum to Assessment report on *Solidago virgaurea* L., herba

Rapporteur(s)	W Dymowski
Peer-reviewer	J Wiesner

HMPC decision on review of monograph on <i>Solidago virgaurea</i> L., herba adopted on 04 September 2008	30 January 2018
Call for scientific data (start and end date)	From 31 March 2018 to 30 June 2018
Adoption by Committee on Herbal Medicinal Products (HMPC)	22 September 2021

Review of new data on *Solidago virgaurea* L., herba

Periodic review (from 2008 to 2021)

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

- Pharmacovigilance data (data from EudraVigilance and VigiBase):
- Scientific/Medical/Toxicological databases: (search date: 06 September 2018):

Regulatory practice

- Old market overview in AR (i.e. products fulfilling 30/15 years on the market)
- New market overview – information from MS.
- Referral
- Ph. Eur. monograph
- Other

Consistency (e.g. scientific decisions taken by HMPC)

- Public statements or other decisions taken by HMPC

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- Consistency with other monographs within the therapeutic area
 Other

Availability of new information (i.e. data likely to lead to a relevant change of the monograph)

<i>Scientific data</i>	Yes	No
New non-clinical safety data likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New clinical safety data likely to lead to a relevant change 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 likely to lead to a relevant change 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 likely to lead to a relevant change 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"/>
Other regulatory practices likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Referrals likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
New Ph. Eur. monograph likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Consistency</i>	Yes	No
New or revised public statements or other HMPC decisions likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Inconsistencies with other monographs within the therapeutic area likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other inconsistencies likely to lead to a relevant change of the monograph	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Summary and conclusions on the review of new data

During the review (using the Mesh term "Solidago virgaurea" and "Goldenrod") were found: in PubMed 242 and 280 hits, in Embase 62 hits and 125 hits, in Medline complete 31 and 104 hits, in ToxNet 14 and 23 hits, in National Toxicology Program no data for both. Complementary search in PubMed for years 2018-2021 revealed 141 hits.

No references were provided by Interested Parties during the Call for data.

No new medicinal products with Solidaginis virgaureae herba as the single active substance have been reported from the MSs. There are seven herbal preparations on the EU market, i.e., herb and dry extracts, 5 in Germany and 2 in Poland. Some products mentioned in the old market overview from

February 2008 are no longer on the market in Germany due to expired marketing authorization or "sunset clause" (the company did not use it for 3 consecutive years).

The reference to the Ph. Eur. monograph on *Solidaginis virgaureae herba* from 2006 was included in the first version of the monograph (2008). The monograph (European Goldenrod) was updated in 2013 to the new one Ph. Eur. 01/2013:1893.

In 2014 a new monograph on *Solidaginis herba* (Goldenrod, Ph. Eur. 04/2014:1892) was added including dried flowering overground parts of *Solidago gigantea* Aiton and/or *Solidago canadensis* L. and its varieties or hybrids and/or mixtures. This has no influence on the content of the monograph for *Solidaginis virgaureae herba* (European Goldenrod).

There is no need to revise the EU herbal monograph due to new regulatory status.

Scientific data

Allergy

In the existing monograph, patients suffering from allergic contact dermatitis due to Compositae species are requested to avoid contacts with *Solidago virgaurea*. This contraindication has also been confirmed by Minciullo *et al.* (2017). Bains *et al.* (2010) reported on cross sensitivity between latex and goldenrod allergy and confirmed this in 3 occupational cases, 2 florists using latex gloves and one health care professional with chronic urticaria and exacerbations reported when sleeping on a latex mattress or gardening. The latex and goldenrod cross reactivity was identified immunologically using serum from patients with strong concomitant latex and goldenrod specific IgE antibody responses.

Assessor's comment:

A contraindication on hypersensitivity for plants from Asteraceae (Compositae) family is already included in the monograph. Bains et al. 2010, described possible latex and goldenrod cross-reactive allergens in three patients. However the findings indicate that exposure to goldenrod may sensitise patients to latex and vice versa, the authors concluded that future studies are needed to define the clinical significance for patients with natural rubber latex allergy who are exposed to goldenrod.

Pharmacovigilance data

The EudraVigilance database contained 28 reports of suspected adverse reactions concerning "*Solidago virgaurea*" or "Goldenrod", among them 2 cases of rash and 2 cases of diarrhoea.

VigiBase (WHO) contained 41 reports (by search) of suspected adverse reactions on "*Solidago virgaurea*" or "Goldenrod", between 01 January 2008 and 03 September 2021.

Assessor's comment:

There are no new safety concerns from the case reports in the EudraVigilance or VigiBase database up to 2021. All the hypersensitivity reactions are covered by the contraindications in section 4.3 of the monograph.

References

a) References relevant for the assessment:

Bains SN, Hamilton RG, Abouhassan S, Lang D, Han Y, Hsieh FH. Identification of clinically relevant cross-sensitization between *Solidago virgaurea* (Goldenrod) and *Hevea brasiliensis* (Natural Rubber Latex). *J Investig Allergol Clin Immunol* 2010, 20(4):331-339

Cai T, Caola I, Tessarolo F, Piccoli F, D'Elia C, Caciagli P, et. al. *Solidago, orthosiphon*, birch and cranberry extracts can decrease microbial colonization and biofilm development in indwelling urinary catheter: a microbiologic and ultrastructural pilot study. *World J Urol* 2014, 32(4):1007-14

Frumenzio E, Maglia D, Salvini E, Giovannozzi S, Di Biase M, Bini V, et. al. Role of phytotherapy associated with antibiotic prophylaxis in female patients with recurrent urinary tract infections. *Arch Ital Urol Androl* 2013, 85(4):197-9

Minciullo PL, Calapai G, Mirodd M, Mannucci C, Chinou I, Gangemi S, et. al. Contact dermatitis as an adverse reaction to some topically used European herbal medicinal products – part 4: *Solidago virgaurea*–*Vitis vinifera*. *Cont Dermatit* 2017, 77:67–87

b) Reference that justify the need for the revision of the monograph:

None

Rapporteur's proposal on revision

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

HMPC decision on revision

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

The HMPC agreed not to revise the monograph, assessment report and list of references on *Solidago virgaurea* L., herba by consensus.