

SUMMARY

fragments F(ab')₂ of European viper antivenom equine immunoglobulin (*Vipera aspis*, *Vipera berus*, *Vipera ammodytes*)

VIPERFAV,

concentrate for solution for infusion

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 18 December 2024

Summary of opinion

Favourable opinion for reimbursement in the treatment of envenomation (grade II or III) by European vipers (*Vipera aspis*, *Vipera berus*, *Vipera ammodytes*), in patients with rapidly spreading oedema and/or systemic signs: vomiting, diarrhoea, abdominal pain and hypotension.

No clinical added value of the new concentrate for solution for infusion form compared to the forms already available.

Transparency Committee's conclusions

Clinical Benefit

- ➔ A grade II or III viper snake envenomation can be life-threatening.
- ➔ This is a curative medicinal product.
- ➔ The efficacy/adverse effects ratio of VIPERFAV is high.
- ➔ This is a first-line treatment in the absence of available therapies in grade II or III viper snake envenomation.

This document and its bibliographic reference are available to download at www.has-sante.fr 

This opinion is published subject to intellectual property rights

Haute Autorité de Santé – Communication and Information Department

5 avenue du Stade de France – 93218 SAINT-DENIS LA PLAINE CEDEX – France. Tel.: +33 (0)1 55 93 70 00

© Haute Autorité de santé – December 2024

→ Public health benefit

VIPERFAV is unlikely to have an additional impact on public health compared to the forms already listed.

The Committee considers that the clinical benefit of VIPERFAV is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication and at the MA dosages.

→ Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%

Clinical Added Value

This medicinal product is a range supplement that does not provide any clinical added value (CAV V) compared to the form already listed.