14 December 2023
EMA/539247/2023
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# VeraSeal

## human fibrinogen / human thrombin

On 14 December 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product VeraSeal. The marketing authorisation holder for this medicinal product is Instituto Grifols, S.A.

The CHMP adopted an extension to the existing indication to include use in all age groups. For information, the full indication will be as follows:[2]

> Supportive treatment in **patients** ~~adults~~ where standard surgical techniques are insufficient:
>
> - for improvement of haemostasis.
>
> - as suture support: in vascular surgery.
>
> **VeraSeal is indicated in all age groups.**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union