14 September 2017
EMA/CHMP/586635/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

VeraSeal

human fibrinogen / human thrombin

On 14 September 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product VeraSeal, intended for use as a sealant during surgical operations in adults. The applicant for this medicinal product is Instituto Grifols, S.A.

VeraSeal (ATC code: B02BC) will be available as solutions containing the active substances human fibrinogen (80 mg/ml) and human thrombin (500 IU/ml). When the two active substances are mixed together, thrombin cuts fibrinogen up into smaller units called fibrin. The fibrin then aggregates and forms a fibrin clot that helps the wound to heal, preventing bleeding.

The benefits of VeraSeal are its ability to help the wound to heal, preventing bleeding. The most common side effects are procedural pain, nausea, pruritus and pyrexia.

The full indication is:

"Supportive treatment in adults where standard surgical techniques are insufficient:

- for improvement of haemostasis.
- as suture support in vascular surgery."

It is proposed that the use of VeraSeal is restricted to experienced surgeons who have been trained in the use of the medicinal product.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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

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