27 June 2013
EMA/CHMP/385035/2013
Committee for Medicinal Products for Human Use (CHMP)

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

# Evarrest

## Human Fibrinogen / Human Thrombin

On 27 June 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product EVARREST Sealant Matrix to Omrix Biopharmaceuticals NV. This recommendation will now be forwarded to the European Commission, which will issue a legally binding decision.

The indication recommended by the CHMP is as follows: *'EVARREST is indicated in adults for supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis'*. EVARREST should only be prescribed by experienced surgeons.

The active substances of EVARREST are human fibrinogen and human thrombin, substances that together help to form a blood clot. They are in a dried form coating the surface of an absorbable composite material (Sealant Matrix). Upon contact with a bleeding wound surface, the fibrinogen and thrombin become activated and form a clot that helps to stop bleeding (haemostasis) and seal the wound.

The CHMP decided that the benefits of EVARREST are greater than its risks following assessment of three main studies that demonstrated haemostasis in soft tissue bleeding in patients undergoing abdominal, retroperitoneal, pelvic or thoracic surgery and also in parenchymal bleeding in patients undergoing hepatic surgery.

Regarding its safety, the most common side effects are haemorrhage and increased fibrinogen, and the most serious adverse reactions were aspiration and pulmonary embolism.

A pharmacovigilance plan for EVARREST will be implemented as part of the marketing authorisation.

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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