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Public statement

Evicel (human fibrinogen / human thrombin)

Withdrawal of the marketing authorisation in the European Union

On 5 July 2024, the European Commission withdrew the marketing authorisation for Evicel (human fibrinogen / human thrombin) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Omrix Biopharmaceuticals N. V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Evicel was granted marketing authorisation in the EU on 6 October 2008 for supportive treatment in surgery, improvement of haemostasis and suture support for haemostasis in vascular surgery. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2013.

Evicel is identical to TachoSil and VeraSeal, which are authorised in the EU for supportive treatment in surgery, improvement of haemostasis and suture support for haemostasis in vascular surgery.

The European Public Assessment Report (EPAR) for Evicel will be updated to indicate that the marketing authorisation is no longer valid.

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