



27 June 2013
EMA/CHMP/393917/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Evicel

Human fibrinogen/Human thrombin

On 27 June 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Evicel. The marketing authorisation holder for this medicinal product is Omrix Biopharmaceuticals N.V. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows: use for suture line sealing in dura mater closure.

Detailed conditions 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 the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Evicel will be as follows²:

EVICEL is used as supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis.

EVICEL is also indicated as suture support for haemostasis in vascular surgery **and for suture line sealing in dura mater closure.**

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

² The text in bold represents the new or the amended indication.

