25 February 2016
EMA/147980/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

TachoSil

human thrombin / human fibrinogen

On 25 February 2016, 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 TachoSil. The marketing authorisation holder for this medicinal product is Takeda Austria GmbH.

The CHMP adopted a new indication as follows[2]:

> "TachoSil is indicated in adults for supportive sealing of the dura mater to prevent postoperative cerebrospinal leakage following neurological surgery".

For information, the full indication for TachoSil will be as follows:

> "TachoSil is indicated in adults for supportive treatment in surgery for improvement of haemostasis, to promote tissue sealing, and for suture support in vascular surgery where standard techniques are insufficient, **and for supportive sealing of the dura mater to prevent postoperative cerebrospinal leakage following neurological surgery**."

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

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