23 February 2023
EMA/CHMP/64876/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

TachoSil

human thrombin / human fibrinogen

On 23 February 2023, 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 Corza Medical GmbH.

The CHMP adopted an extension to existing indication as follows:[2]

> TachoSil is indicated in adults **and children from 1 month of age** 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.
>
> TachoSil is indicated in adults for supportive sealing of the dura mater to prevent postoperative cerebrospinal leakage following neurological surgery (see section 5.1).

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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