European Medicines Agency
Evaluation of Medicines for Human Use

London, 18 December 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
TACHOSIL

International Nonproprietary Name (INN): ***human fibrinogen / human thrombin***

On 18 December 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product TachoSil. The Marketing Authorisation Holder for this medicinal product is Nycomed Austria Gmbh.

The CHMP adopted *new indications* as follows:
"to promote tissue sealing and for suture support in vascular surgery".

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) 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 indication for TachoSil will be as follows***:
TachoSil is indicated 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 (see SPC section 5.1)".

* 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.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.europa.eu http://www.emea.europa.eu