1st February 2016

IMPORTANT INFORMATION

TachoSil (human fibrinogen/human thrombin): new recommendations to mitigate the risk of intestinal obstruction

Dear Healthcare Professional,

In agreement with the European Medicines Agency (EMA) and Health Products Regulatory Authority (HPRA), Takeda would like to inform you of the risk of adhesions to gastrointestinal tissues, leading to intestinal obstruction, associated with TachoSil. New recommendations for use are introduced in order to mitigate this risk.

Summary:

- **Cases of adhesions to gastrointestinal tissues leading to gastrointestinal obstruction have been reported with use of TachoSil in abdominal surgery carried out in proximity to the bowel.**
- **To prevent tissue adhesions at undesired sites, please ensure tissue areas outside the desired application area are adequately cleansed of residual blood before administration of TachoSil.**
- **For appropriate application of TachoSil, please refer to the enclosed updated product information and "Instructions for Use".**

Further background information to this safety update:

TachoSil is a medicinal product that contains the active substances human fibrinogen and human thrombin coated onto a collagen patch. TachoSil was first approved in the EU in 2004, and is indicated in surgery to improve haemostasis, promote tissue sealing, and for suture support in vascular surgery where standard techniques are insufficient.

Upon request of the EMA, Takeda has evaluated all reports referring to intestinal obstruction associated with the use of TachoSil. The evaluation concluded a plausible causal relationship between application of TachoSil and gastrointestinal adhesions leading to obstruction. Due to the strong affinity of collagen to blood, TachoSil may stick to adjacent tissues covered with blood if the surgical site is inadequately prepared and/or not cleansed of residual blood or if TachoSil is applied inappropriately.

Call for Adverse Reaction/Event reporting

Please report any suspected adverse reactions, including any incorrect application of TachoSil to the HPRA via the national spontaneous reporting system to HPRA Pharmacovigilance, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland. Tel: 01 676 4971. Fax 01 676 2517. Website www.hpra.ie. E-mail: medsafety@hpra.ie

When reporting please ensure to include the name of the product administered.

Should you have any questions or product complaints concerning the use of TachoSil or questions about the content of this letter, please contact Takeda UK Ltd:

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Tel: 01628 537900, Fax: 01628 526617, Email: DSO-UK@takeda.com, Website: www.takeda.co.uk

Yours sincerely,

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Annexes
Annex 1: Relevant sections of the "Summary of Product Characteristics" that have been revised (amendments to the text are indicated in **bold**)
Annex 2: Updated "Instructions for Use"