

הודעה על החמרה (מידע בטיחות) בעלון לרופא

15.2.17

תאריך

שם תכשיר באנגלית ומספר הרישום :

Tachosil 139-51-31704-00

שם בעל הרישום _____ כצט בע"מ

טופס זה מיועד לפרוט החמרות בלבד !

החמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p>For epilepsional use only.</p> <p>Do not use intravascularly. Life threatening thromboembolic complications may occur if the preparation is applied intravascularly</p> <p>Specific data have not been obtained on the use of this product in neurosurgery, or in gastrointestinal anastomoses surgery.</p> <p>As with any protein-containing product, allergic type hypersensitivity reactions are possible. Signs of hypersensitivity reactions include hives, generalised urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis. If these symptoms occur, the administration has to be discontinued immediately.</p> <p style="background-color: yellow;">To prevent the development of tissue adhesions at undesired sites, ensure tissue areas outside the desired application area are adequately cleansed before administration of TachoSil (see section 6.6). Events of adhesions to gastrointestinal tissues leading to gastrointestinal obstruction have been reported with use in abdominal surgery carried out in proximity to the bowel.</p> <p>In case of shock, the current medical standards for shock treatment should be observed.</p>	<p>For local use only.</p> <p>Do not use intravascularly. Life threatening thromboembolic complications may occur if the preparation is unintentionally applied intravascularly</p> <p>Specific data have not been obtained on the use of this product in neurosurgery, or in gastrointestinal anastomoses surgery.</p> <p>As with any protein product, allergic type hypersensitivity reactions are possible. Signs of hypersensitivity reactions include hives, generalised urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis. If these symptoms occur, the administration has to be discontinued immediately.</p> <p>In case of shock, the current medical standards for shock treatment should be observed.</p>	<p>Special warnings and special precautions for use</p>
<p>Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the application site, bronchospasm, chills, flushing, generalised urticaria, headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia, tightness of the chest, tingling, vomiting, wheezing) may occur in rare cases in</p>	<p>Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the application site, bronchospasm, chills, flushing, generalised urticaria, headache, hives, hypotension, lethargy, nausea, restlessness,</p>	<p>Undesirable effects</p>

<p>patients treated with fibrin sealants/haemostatics. In isolated cases, these reactions may progress to severe anaphylaxis. Such reactions may especially be seen, if the preparation is applied repeatedly, or administered to patients known to be hypersensitive to constituents of the product.</p> <p>Immunogenicity: Antibodies against components of fibrin sealant/haemostatic products may occur rarely.</p> <p>However in a clinical trial with TachoSil in hepatic surgery, in which patients were investigated for the development of antibodies, about 26% of the 96 patients tested and treated with TachoSil developed antibodies to equine collagen. The equine collagen antibodies that developed in some patients after TachoSil use were not reactive with human collagen. One patient developed antibodies to human fibrinogen. There were no adverse events attributable to the development of human fibrinogen or equine collagen antibodies.</p> <p>There is very limited clinical data available regarding re-exposure of TachoSil. Two subjects have been re-exposed in a clinical trial and have not reported any immune-mediated adverse events, however, their antibody status to collagen or fibrinogen is unknown.</p> <p>Thromboembolic complications may occur if the preparation is unintentionally applied intravascularly.(see section 4.4)</p> <p>.</p> <p>.</p> <p>.</p> <p>The following adverse reactions have been reported with TachoSil during post marketing experience. The frequency of all of the events listed below has been categorised as not known (cannot be estimated from the available data).</p> <p>Hypersensitivity Thrombosis Anaphylactic shock Intestinal obstruction (in abdominal surgeries) Adhesions</p>	<p>tachycardia, tightness of the chest, tingling, vomiting, wheezing) may occur in rare cases in patients treated with fibrin sealants/haemostatics. In isolated cases, these reactions may progress to severe anaphylaxis. Such reactions may especially be seen, if the preparation is applied repeatedly, or administered to patients known to be hypersensitive to constituents of the product.</p> <p>Antibodies against components of fibrin sealant/haemostatic products may occur rarely.</p> <p>Thromboembolic complications may occur if the preparation is unintentionally applied intravascularly.(see section 4.4)</p> <p>.</p> <p>.</p> <p>The following adverse reactions have been reported with TachoSil during post marketing experience. The frequency of all of the events listed below has been categorised as not known (cannot be estimated from the available data).</p> <p>Hypersensitivity Thrombosis</p>	
<p>re is applied with moistened gloves or a moist pad. Due to the strong affinity of collagen to blood, TachoSil may also stick to surgical instruments, gloves or adjacent tissues covered with blood. This can be avoided by pre- cleansing surgical instruments and gloves and adjacent tissues before application. It is important to note that failure to adequately clean adjacent tissues may cause adhesions (see section 4.4).After pressing TachoSil to the wound, the glove or the pad must be removed carefully. To avoid the matrix from being pulled loose it may be held in place at</p>	<p>re is applied with moistened gloves or a moist pad. Due to the strong affinity of collagen to blood, TachoSil may also stick to surgical instruments or, gloves covered with blood. This can be avoided by pre-moistening surgical instruments and gloves with physiological saline solution After pressing TachoSil to the wound, the glove or the pad must be removed carefully. To avoid the sponge from being</p>	<p>Instructions for use and handling and disposal</p>

one end, e.g. with a pair of forceps.

pulled loose it may be held in place at one end, e.g. with a pair of forceps.

