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TachoSil (*human fibrinogen / human thrombin*)

An overview of TachoSil and why it is authorised in the EU

What is TachoSil and what is it used for?

TachoSil is a sponge sealant patch used in adults and children from 1 month of age:

- during an operation, to stop bleeding and seal the surfaces of internal organs;
- as a support to stitching during surgery on blood vessels when standard techniques are not sufficient.

TachoSil is also used in adults during neurological surgery to seal the dura mater (a membrane that surrounds and protects the brain) to prevent leakage of the fluid surrounding the brain (called cerebrospinal fluid or CSF).

The TachoSil patch is coated with the active substances human fibrinogen and human thrombin.

How is TachoSil used?

TachoSil should only be used by an experienced surgeon under sterile conditions.

TachoSil should only be applied directly onto the treatment site. The sponge should be applied so that it covers 1 to 2 cm beyond the edge of the wound. The size and number of TachoSil sponges to be used depends on the size of the wound. Sponges can be cut to size if needed. TachoSil must not be applied inside a blood vessel.

For more information about how TachoSil is used, see the package leaflet or contact your healthcare provider.

How does TachoSil work?

The active substances in TachoSil, fibrinogen and thrombin, are blood proteins involved in the natural clotting process. Thrombin works by converting fibrinogen into smaller units called fibrin, which then stick together to form a local clot.

When TachoSil is applied to a bleeding area during surgery, the moisture causes the active substances to react together, leading to the rapid formation of a clot. The clot enables the patch to stick more firmly to the tissue, helping to stop the bleeding and sealing the wound.

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In neurological surgery, it works by sealing together the cut areas of the outermost layer (dura mater) of the membranes around the brain. This way, it prevents the CSF from leaking.

The TachoSil patch is left in the body, where it dissolves and disappears completely.

What benefits of TachoSil have been shown in studies?

Two studies looked at the effects of TachoSil in stopping bleeding. The studies compared the effects of TachoSil and an argon beamer (a device that sears the cut surface and reduces bleeding) in 240 adults having liver surgery. The main measure of effectiveness was the time until the bleeding stopped. TachoSil was more effective than the argon beamer at stopping bleeding during liver surgery. In the first study, the average time until bleeding stopped was 3.9 minutes with TachoSil compared with 6.3 minutes with the argon beamer, and in the second study, these values were 3.6 and 5.0 minutes, respectively.

A third study compared TachoSil with standard stitching in 185 patients having kidney surgery. The main measure of effectiveness was the time until the bleeding stopped. TachoSil was more effective than stitching at stopping bleeding during kidney surgery. The average time until bleeding stopped was 5.3 minutes with TachoSil compared with 9.5 minutes with standard stitching.

Two additional studies were carried out to test if TachoSil could be used as a tissue sealant. The studies compared TachoSil and standard surgical techniques, such as stitching and stapling, in a total of 490 patients having lung surgery. Effectiveness was measured by looking at whether air leaked from the lungs after surgery. The first study was not sufficient to support the use of TachoSil in sealing tissue since very few patients in the study had any air leakage. However, in the second study, which involved 301 patients, it took an average of 15.3 hours for leakage to stop with TachoSil compared with 20.5 hours with current techniques.

A sixth study looked at the effectiveness of TachoSil in surgery on the heart or major blood vessels. The study compared TachoSil with standard materials in 120 patients, of whom around three-quarters also had surgery on vessels with stitches and one-quarter had surgery on the heart. The main measure of effectiveness was the number of patients whose bleeding had stopped after three minutes. TachoSil was also more effective than standard materials at stopping bleeding during surgery on the heart and blood vessels. After three minutes, bleeding had stopped in 75% of the patients treated with TachoSil (44 out of 59), compared with 33% of those treated with standard techniques (20 out of 60).

A seventh study involved 726 patients and compared TachoSil with current techniques used in daily practice in preventing CSF leakage during neurological surgery. TachoSil was comparable to current techniques: around 7% (25 out of 361) of patients treated with TachoSil had a leak of CSF, compared with around 8% (30 out of 365) of patients on current techniques.

There are limited data available on the use of TachoSil in children. However, data from two studies which involved a limited number of children and additional information from the medical literature show that TachoSil can also be used in children for sealing tissues and blood vessels during surgery.

What are the risks associated with TachoSil?

For the full list of all side effects and restrictions with TachoSil, see the package leaflet.

TachoSil may cause an allergic reaction, thrombosis (blood clots), a blockage in the intestine when used during abdominal surgeries, the formation of scar tissue and foreign body granuloma (a type of inflammatory reaction). Patients may also develop antibodies to the proteins in TachoSil, which could reduce its ability to stop bleeding. These side effects are rare and their frequency is not known.

TachoSil must not be applied inside a blood vessel as this may lead to thromboembolic complications (blood clots in vessels).

Why is TachoSil authorised in the EU?

TachoSil has been shown to be effective in adults and children from 1 month of age as a supportive treatment during surgery to seal the surfaces of internal organs, promote blood clotting, reduce bleeding and support sutures during surgery on blood vessels when standard techniques are insufficient. TachoSil has also been shown to be effective in adults during neurological surgery to prevent leakage of the CSF. In addition, observed side effects of TachoSil are rare. Therefore, the European Medicines Agency decided that TachoSil's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of TachoSil?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of TachoSil have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of TachoSil are continuously monitored. Suspected side effects reported with TachoSil are carefully evaluated and any necessary action taken to protect patients.

Other information about TachoSil

TachoSil received a marketing authorisation valid throughout the EU on 8 June 2004.

Further information on TachoSil can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Tachosil.

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