

Package leaflet: Information for the user

TachoSil sealant matrix human fibrinogen/human thrombin

Read all of this leaflet carefully.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What TachoSil is and what it is used for
2. What you need to know before TachoSil is used.
3. How to use TachoSil
4. Possible side effects
5. How to store TachoSil
6. Contents of the pack and other information

1. What TachoSil is and what it is used for

How does TachoSil work?

The yellow side of TachoSil contains the active components: fibrinogen and thrombin. The **yellow** side of TachoSil is therefore the **active side**. When the active side comes into contact with fluids (such as blood, lymph or saline solution) the fibrinogen and the thrombin are activated and form a fibrin network. This means that the TachoSil sticks to the tissue surface, the blood coagulates (local haemostasis) and the tissue is sealed. In the body TachoSil will dissolve and disappear completely.

What is TachoSil used for?

TachoSil is used during surgery to stop local bleeding (haemostasis) and to seal tissue surfaces on internal organs.

2. What you need to know before TachoSil is used

Do not use TachoSil

- if you are allergic (hypersensitive) to human fibrinogen, human thrombin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

TachoSil is for local use only and should not be applied inside a blood vessel. Blood clots may occur if TachoSil is unintentionally applied inside a blood vessel.

It is possible that you could suffer an allergic reaction after TachoSil has been applied. You may suffer hives, or a rash similar to nettle rash, chest discomfort or tightness, wheezing or low blood pressure.

You should contact your doctor immediately if you discover any of these symptoms.

After abdominal surgery and if TachoSil sticks to nearby tissues, it is possible that scar tissues can develop in the operated area. Scar tissues can cause surfaces in your bowel to stick together, which can lead to blockage of the bowel.

When medicines are made from human blood or plasma, certain measures are put in place to prevent

infections being passed on to the patients. These include careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded, and the testing of each donation and pools of plasma for signs of virus/infections. Manufacturers of these products also include steps in the processing of the blood or plasma that can inactivate or remove viruses. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus, and for the non-enveloped hepatitis A virus. The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19. Parvovirus B19 infection may be serious for pregnant woman (foetal infection) and for individuals whose immune system is depressed or who have some types of anaemia, (e.g. sickle cell disease or haemolytic anaemia).

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Other medicines and TachoSil

Tell your doctor if you are taking, have recently taken or might take any other medicines.

3. How to use TachoSil

The doctor treating you will apply TachoSil during surgery. The quantity of TachoSil used depends on the size of the wound. The doctor will place TachoSil on the internal organ to stop the bleeding or to seal the tissue. During the following time TachoSil will dissolve and disappear.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

TachoSil is made of protein-containing components. The active components are made from human blood. All medicines based on human blood may uncommonly cause allergic reactions. In isolated cases these allergic reactions may progress to anaphylactic shock.

These allergic reactions may occur especially if TachoSil is used repeatedly or if you are allergic to any of the ingredients in TachoSil.

A clinical study has shown that some patients produced antibodies against the components of TachoSil, however, no side effects were reported resulting from the development of these antibodies.

Scar tissues may develop in some patients after surgery and use of TachoSil. Bowel obstruction and pain following abdominal surgeries can also occur. The frequency of these types of events is not known (cannot be estimated from available data). Your surgeon will make sure to clean the operating area when applying TachoSil to reduce this risk.

Reporting of side effects

If you get any side effects, talk to your doctor, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to:

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TachoSil

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What TachoSil contains

- The active substances are human fibrinogen (5.5 mg per cm²) and human thrombin (2.0 IU per cm²).
- The other ingredients are equine collagen, human albumin, riboflavin (E101), sodium chloride, sodium citrate (E331) and L-arginine-hydrochloride.

What TachoSil looks like and contents of the pack

TachoSil is a sealant matrix made of collagen, which is coated on the yellow side with human fibrinogen and human thrombin.

The product is available in different sizes and comes in packages with up to 5 units:

Package with 1 matrix of 9.5 cm x 4.8 cm

Package with 2 matrices of 4.8 cm x 4.8 cm

Package with 1 matrix of 3.0 cm x 2.5 cm

Package with 5 matrices of 3.0 cm x 2.5 cm

Package with 1 pre-rolled matrix of 4.8 cm x 4.8 cm

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Takeda Austria GmbH

St. Peter Strasse 25

A-4020 Linz, Austria

This leaflet was last revised in December 2019.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for medical or healthcare professionals only:

INSTRUCTIONS FOR USE

Read this before you open the package:

TachoSil comes in sterile packages and therefore it is important:

- *only* to use undamaged packages which have not been opened (post-sterilisation is not possible).
- to have a *non-sterile person* open the outer aluminium cover
- to have a *sterile person* open the inner sterile package
- to use TachoSil *soon after* opening the outer aluminium cover.
- to use TachoSil *immediately* after opening the inner sterile package.

Instructions

Use TachoSil under sterile conditions only.

Find out which size of TachoSil is needed. The size of the sealant matrix depends on the size of the wound. But please note that the matrix should cover 1-2 cm beyond the margins of the wound. If more than one matrix is needed, they should overlap. For smaller wounds, e.g. in minimally invasive surgery, the smaller sizes (4.8 x 4.8 cm or 3.0 x 2.5 cm) or the pre-rolled TachoSil (4.8 cm x 4.8 cm) is recommended. TachoSil can be cut to the appropriate size and shaped to fit the wound.

1. Wipe the wound surface gently before placing TachoSil on the wound. Strong (pulsating) bleeding should be stopped surgically.
2. Open the inner sterile package and remove the matrix. Pre-moisten the flat TachoSil matrix in saline solution and place it on the wound immediately (if the wound is completely wetted by blood and other fluids, there is no need to moisten the matrix before application). The pre-rolled TachoSil should **not** be pre-moistened before passing through the trocar or port.
3. Cleanse surgical instruments, gloves and adjacent tissues, if necessary. TachoSil may stick to surgical instruments, or gloves or adjacent tissues covered with blood. It is important to note that failure to adequately clean adjacent tissues may cause adhesions.
4. If a trocar is used for getting access to the wound, the inside of the trocar should be dry. It is recommended to remove the top part of the trocar prior to passing the pre-rolled TachoSil through the trocar.
5. Place the **yellow, active side** of TachoSil against the wound. Hold down TachoSil with a gentle pressure for 3-5 minutes. Use a moistened glove or a moist pad to keep TachoSil in place. For minimally invasive surgery, the pre-rolled matrix can be un-rolled with instruments at the site of application. The un-rolled TachoSil should then be moistened at the site of application with a moist pad and held in place under gentle pressure for 3-5 minutes.
6. Remove the light pressure carefully after 3-5 minutes. To make sure that TachoSil does not cling to the moistened glove or swab, and loosens itself from the wound, TachoSil can be held down at one end e.g. by using a pair of forceps. There is no residual product which needs to be removed; the entire matrix is dissolved (resorbed).

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