Applicant: MC Pharma (Pty) Ltd.
Product name: TachoSil
Dosage form: sealant matrix
Strength(s): Each sealant matrix contains: Human Fibrinogen 5,5 mg and Human Thrombin 2,0 IU

19 August 2025

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **4**

TachoSil sealant matrix

Read all of this leaflet carefully before you are given TachoSil

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What **TachoSil** is and what it is used for
2. What you need to know before you use **TachoSil**
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).

It is strongly recommended that when you receive TachoSil the name and batch number of the product are recorded at the hospital in order to maintain a record of the batches used.

Other medicines and TachoSil

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional 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

TachoSil medicine can have side effects.

Not all side-effects reported for TachoSil are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TachoSil, please consult your health care provider for advice.

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, pain and ileus (slowing of gut movement causing nausea, vomiting, stomach discomfort, bloated stomach or severe constipation) 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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TachoSil.

5. How to store TachoSil

Store all medicines 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. Return all unused medicine to your pharmacist. 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 cm^2) and human thrombin (2.0 IU per cm^2).
- 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.

Holder of Certificate of Registration

MC Pharma (Pty) Ltd.
62 Constantia Avenue
Mnandi
Centurion 0149
Tel: 012 668 3019

This leaflet was last revised in

19 August 2025

Registration number

45/8.1/0937