

TachoSil® Medicated Sponge

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given TachoSil?

TachoSil contains the two active ingredients fibrinogen and human thrombin. TachoSil is used during surgery to stop local bleeding (haemostasis).

For more information, see Section [1. Why am I using TachoSil?](#) in the full CMI.

2. What should I know before I am given TachoSil?

Do not use if you have ever had an allergic reaction to TachoSil or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use TachoSil?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TachoSil and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is TachoSil given?

- The surgeon treating you will administer TachoSil during surgery.

More instructions can be found in Section [4. How do I use TachoSil?](#) in the full CMI.

5. What should I know after I have received TachoSil?

Things you should do	<ul style="list-style-type: none">• If you are going to have surgery, tell the surgeon or anaesthetist that you have received TachoSil.• Keep all of your doctor's appointments so that your progress can be checked.
Storing the medicine	<ul style="list-style-type: none">• TachoSil should be stored by the hospital in a place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

The more common side effects of this medicine are fever and changes in the way your heart beats.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TachoSil® Medicated Sponge

Active ingredients: *fibrinogen and human thrombin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TachoSil. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TachoSil.**

Where to find information in this leaflet:

- [1. Why am I being given TachoSil?](#)
- [2. What should I know before I am given TachoSil?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is TachoSil given?](#)
- [5. What should after I have received TachoSil?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given TachoSil?

TachoSil contains the two active ingredients **fibrinogen and human thrombin**, which are proteins normally found in the blood.

TachoSil is used during surgery to stop local bleeding (haemostasis).

When the sponge comes into contact with fluids (such as blood, lymph or saline solution) the fibrinogen and the human thrombin are activated and form a fibrin network.

This means that the sponge sticks to the tissue surface, the blood coagulates and the tissue is sealed.

In the body, TachoSil will dissolve and disappear completely.

Ask your doctor if you have any questions about why this medicine has been recommended for you.

Your doctor may have prescribed it for another reason.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

2. What should I know before I am given TachoSil?

Warnings

Do not use TachoSil if you have an allergy to:

- any medicine containing fibrinogen or human thrombin
- any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction include:

- shortness of breath

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

TachoSil is not intended to be given intravascularly.

Intravascular application of TachoSil may result in life-threatening thromboembolic events.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have allergies to any other medicines, food preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with TachoSil and affect how it works.

4. How is TachoSil given?

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

The surgeon treating you will administer TachoSil during surgery.

The sponge will be placed on the internal organ to stop the bleeding.

The sponge will disappear and dissolve completely over time.

How much will be given

- Your doctor will determine the number of TachoSil sponges required, which will depend on the size of the wound.

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

5. What should I know after I have received TachoSil?

Things you should do

- **If you are going to have surgery, tell the surgeon or anaesthetist that you have received TachoSil.**
It may affect other medicines used during surgery.
- **Tell your doctor immediately if you become pregnant soon after receiving TachoSil.**
- Keep all of your doctor's appointments so that your progress can be checked.

Storing the medicine

TachoSil should be stored by the hospital in a place where the temperature stays below 25°C.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General: <ul style="list-style-type: none"> • Fever Heart-related: <ul style="list-style-type: none"> • Changes in the way your heart beats 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reaction: <ul style="list-style-type: none"> • Shortness of breath, wheezing or difficulty breathing • Swelling of the face, lips, tongue or other parts of the body • Rash, itching or hives on the skin Viral infection: <ul style="list-style-type: none"> • Fever, drowsiness, chills and runny nose followed about two weeks later by a rash and joint pain Abdomen-related:	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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| • Pain in your abdomen or bowels | |
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Tell your doctor as soon as possible if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only to be used by surgeons.

What TachoSil contains

Active ingredients (main ingredients)	Each square centimetre of the sponge contains: <ul style="list-style-type: none"> • 5.5 mg fibrinogen • 2.0 IU human thrombin
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • collagen • albumin • riboflavine • sodium chloride • sodium citrate dihydrate • arginine hydrochloride

Do not take this medicine if you are allergic to any of these ingredients.

What TachoSil looks like

TachoSil is an off-white sponge, coloured yellow on the active side (AUST R 176631).

It is available in the following dimensions and pack sizes:

- 1 sponge of 9.5 cm x 4.8 cm
- 2 sponges of 4.8 cm x 4.8 cm
- 1 sponge of 3.0 cm x 2.5 cm
- 5 sponges of 3.0 cm x 2.5 cm

Who distributes TachoSil

Sponsor:

Adjutor Healthcare Pty Ltd
3 Grandview Avenue, Point Cook
VIC 3030, Australia
www.adjutor.com.au

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