

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, nurse or pharmacist.

1. Why am I receiving TISSEEL?

TISSEEL is a fibrin sealant with the active ingredients fibrinogen, thrombin, aprotinin, factor XIII and calcium chloride dihydrate. It is used to help stop excessive blood loss during surgery, and as a 'tissue glue' in certain types of surgery.

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

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

Do not use if you have ever had an allergic reaction to aprotinin 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 am given TISSEEL?](#) in the full CMI.

3. What if I am taking other medicines?

There are currently no medicines known to interact with TISSEEL.

See Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is TISSEEL used?

- Your surgeon will apply TISSEEL as needed during your surgical operation.
- Your surgeon will decide how much TISSEEL will be applied, depending on your individual need.
- More instructions can be found in Section [4. How is TISSEEL used?](#) in the full CMI.

5. What should I know after having TISSEEL?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Talk to your doctor and surgeon about how you feel after your surgical operation.• Remind any doctor, dentist or pharmacist you visit that you have received TISSEEL during a previous surgical procedure. |
| Looking after your medicine | <ul style="list-style-type: none">• This medicine is stored in the hospital pharmacy, kept at minus 18 °C or colder and protected from light. Medical professionals handle, prepare and use it according to the manufacturer's instructions.• You will not have to store or handle this medicine. |

For more information, see Section [5. What should I know after having TISSEEL?](#) in the full CMI.

6. Are there any side effects?

Serious side effects include sudden allergic reactions (early symptoms can be flushing, increased or decreased pulse rate, hives, itching, or difficulty breathing). Allergic reactions are more likely if you have received TISSEEL in previous surgery. Allergic reactions can be life-threatening.

Products like TISSEEL can be applied with spray devices. Improper use of spray devices can cause air to get into the blood circulation. This side effect can be life-threatening.

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.

TISSEEL (frozen) fibrin sealant syringe

Active ingredients: fibrinogen, thrombin, aprotinin, factor XIII, and calcium chloride dihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using TISSEEL. **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 TISSEEL.**

Where to find information in this leaflet:

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

1. Why am I receiving TISSEEL?

TISSEEL is a **fibrin sealant** containing the active ingredients fibrinogen, thrombin, aprotinin, factor XIII, and calcium chloride dihydrate.

TISSEEL is used to help stop blood loss during surgery by making a clot, which is very similar to a natural blood clot. This clot adheres firmly to tissue, acting as a kind of 'tissue glue'.

Because of its glue-like properties, TISSEEL can also be used:

- to help close openings of the colon from outside the body (colostomies)
- as an aid in some cartilage repair procedures
- in hernia repair procedures.

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

Warnings

You should not be given TISSEEL if:

- you are hypersensitive to aprotinin, or any of the ingredients listed at the end of this leaflet.

Check with your doctor if you:

- have any other medical conditions
- tend to have allergic reactions
- take any medicines for any other condition
- have been given aprotinin or fibrin sealant in a previous surgical operation.

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.

Use in children

The safety and effectiveness of TISSEEL in children have not been established.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TISSEEL.

There are currently no medicines known to interact with TISSEEL.

4. How is TISSEEL USED?

How it is used

- Your surgeon will apply TISSEEL as needed during your surgical operation.

How much is given

- Your surgeon will decide how much TISSEEL will be applied, depending on your individual need.

If too much TISSEEL is used

Your surgeon applies TISSEEL only on the tissue surface (local application). It is unlikely that your surgeon will use too much (overdose).

5. What should I know after having TISSEEL?

Things you should do

Talk to your doctor and surgeon about how you feel after your surgical operation.

Since TISSEEL is given in a hospital, your healthcare provider will monitor your progress and any side effects.

Looking after your medicine

You will not have to store or handle this medicine.

This medicine is stored in the hospital pharmacy, kept at minus 18 °C or colder and protected from light. Medical professionals handle, prepare and use it according to the manufacturer's instructions.

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 |
|---|--|
| <p>Skin-related:</p> <ul style="list-style-type: none"> itching cyst <p>Infection-related</p> <ul style="list-style-type: none"> fever or chills runny nose drowsiness <p>Followed about two weeks later by:</p> <ul style="list-style-type: none"> rash or joint pain <p>Others:</p> <ul style="list-style-type: none"> feeling tired low fever <p>Followed by</p> <ul style="list-style-type: none"> yellowed complexion nausea, vomiting and abdominal pain | <p>Speak to your doctor if you have any of these less serious side effects.</p> |

Serious side effects

| Serious side effects | What to do |
|--|---|
| <p>Allergic reaction-related:</p> <ul style="list-style-type: none"> swelling of the face, eyes, lips, mouth or throat rash difficulty in swallowing or breathing a slow or a rapid pulse nausea, vomiting or diarrhoea dizziness or fainting red skin or flushing itchy skin pins and needles application site irritation drowsiness restlessness <p>Procedure-related:</p> <ul style="list-style-type: none"> graft failure | <p>Call the doctor on duty straight away if you notice the symptoms of an allergic reaction.</p> <p>Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Tell your doctor or pharmacist 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 available with a doctor's prescription. It is only used in a hospital setting, during specific surgical operations.

What TISSEEL contains

TISSEEL contains synthetic and human plasma proteins. Human proteins have been isolated from the pooled blood of healthy donors according to World Health Organisation (WHO) guidelines.

TISSEEL contains two components, the **Sealer Protein Solution** and the **Thrombin Solution** (see table below). The two components are filled in two separate chambers of a double-chamber syringe.

| | |
|---|---|
| Active ingredients - (main ingredients) | <p>Sealer Protein Solution</p> <ul style="list-style-type: none"> Fibrinogen (human) Factor XIII (human) Aprotinin (synthetic) <p>Thrombin Solution</p> <ul style="list-style-type: none"> Thrombin (human) Calcium Chloride Dihydrate |
| Other ingredients (inactive ingredients) | <p>Sealer Protein Solution</p> <p>Human Albumin, Histidine, Sodium Citrate, Polysorbate 80, Nicotinamide, Water for Injections</p> <p>Thrombin Solution</p> <p>Sodium Chloride, Human Albumin, Water for Injections</p> |
| Potential allergens | Aprotinin |

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

What TISSEEL looks like

TISSEEL is a frozen, two-component fibrin sealant, supplied in a single-use double-chamber syringe packed in two bags and one device set with 2 joining pieces and 4 application cannulas.

TISSEEL is available in 2.0 mL, 4.0 mL, and 10.0 mL package sizes. (Aust R 147141).

Who distributes TISSEEL

Baxter Healthcare Pty Ltd

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Old Toongabbie

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This leaflet was prepared in June 2025.

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