TISSEEL

((frozen) fibrin sealant syringe)

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about the TISSEEL Fibrin Sealant, Two-Component Fibrin Sealant, Deep-Frozen, Vapour Heated (VH) and Solvent Detergent (S/D) Treated [TISSEEL Fibrin Sealant]. It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks against the benefits for you of using TISSEEL.

It does not take the place of talking to your doctor or pharmacist. If you have any concerns about using this medicine, ask your doctor or pharmacist.

What TISSEEL is used for?

TISSEEL is used to help stop excessive blood loss during surgery by inducing clotting. This clot has also sealing and fixation properties. Thus, it can also be used as an aid to help in the closure of colostomies and as an aid in some cartilage repair procedures and for use in hernia repair procedures.

How does TISSEEL work?

The blood coagulation factors in the composition of TISSEEL are the same as those found in normal healthy individuals. They are isolated from healthy human plasma, except aprotinin, which is a synthetic component. The components are packed in a double-chamber syringe. One of the chamber contains Sealer Protein solution while the other contains Thrombin solution. The double-chamber syringe is stored in a deep frozen state. It will be warmed up to 33°C - 37°C just prior to use.

Before you are given TISSEEL

TISSEEL should not be given to you if:

- you have a tendency to allergic reactions or hypersensitivity to aprotinin. Some of the symptoms of an allergic reaction may include skin rash, swelling of the face, lips or tongue, which may cause difficulty swallowing or shortness of breath
- the expiry date printed on the pack has passed

You must tell your doctor if you:

- have any other illness
- are taking any prescription medicine or any other medicines purchased from a pharmacy, health food store or supermarket
- have previously received aprotinin or fibrin sealant, whether you are allergic to it or not
- you have allergies to aprotinin or other components of TISSEEL

You must tell your doctor if you are pregnant, planning to become pregnant or breast-feeding.

The use of TISSEEL during your surgical operation under either of these conditions is not recommended, due to insufficient information in support of such usages. If there is a need to consider the use of this product during pregnancy or breast-feeding, your doctor will discuss the risks and benefits with you.

Use in children

Safety of use in children has not been established.

How TISSEEL is given?

How much is given:

Your surgeon will decide how much TISSEEL will be given to you, which depends on your need and condition.

How it is given:

TISSEEL is for the surgeon's use during an operation only. Your surgeon will apply it using a special device for delivery of that medication. For health professionals, details are described in the Product Information.

Case of overdose:

TISSEEL is used only for local application and thus the case of overdose is unlikely to occur.

While you are treated with TISSEEL

Discuss with your doctor and surgeon the progress you have experienced after the treatment, especially during the first few days after surgery. As TISSEEL is given in a hospital, your healthcare professional will take records of the progress and unexpected reactions.

Side effects

As with any medicine, some side effects may occur. Some patients may have sudden signs of allergy. This is more likely if the product has been used in previous surgery. Your surgeon is aware of this potential adverse effect. If any of the following happen, for example, rash, swelling of the face, lips, mouth or difficulty in breathing, tell your health professional on duty immediately. In exceptional cases symptoms of a serious allergic reaction may occur, known as "anaphylactic shock". Then, your healthcare professional will take an appropriate action promptly to reverse the symptoms.

You must tell your doctor if you have fever, drowsiness, chills and runny nose followed by rash and joint pain that may develop about two weeks after your surgery. Similarly you must tell your doctor if you have dark urine, yellowed complexion, feel tired and have low grade fever followed by nausea, vomiting and abdominal pain.

Product description

What TISSEEL looks like?

It is presented in a preloaded double-chamber syringe package under deep-frozen state. Each pack of TISSEEL contains accessory devices used for simultaneous application of the contents of both chambers of the syringe. They are packed under sterile conditions and presented in a deep-frozen state, at -18°C or colder.

What is in TISSEEL?

The active components of TISSEEL are plasma proteins isolated from pooled human blood of healthy donors according to WHO guidelines. The active components are filled in two separate chambers of a double-chamber syringe, (1) Sealer Protein solution and (2) Thrombin solution, as shown below:

	Sealer Protein solution	Thrombin Solution
Active Ingredients	-Aprotinin (synthetic) -Factor XIII -Fibrinogen	-Thrombin (human) -Calcium chloride (2 H_2O)
Excipients	-Albumin (human) -Histidine -Nicotinamide -Polysorbate 80 -Sodium citrate -Water for injections	-Albumin (human) -Sodium chloride -Water for injections

How to store TISSEEL?

TISSEEL is presented in a deep frozen state at -18 °C or colder in a hospital pharmacy. The cold storage chain must not be interrupted until use. Keep container in the outer carton to protect from light.

Unopened pouches, thawed at 25°C, may be stored for up to 72 hours at or below 25°C after removal from the freezer. After thawing, the solution must not be refrozen.

If the product is removed from original pouch or warmed to 33 - 37°C, it must be used within 12 hours.

TISSEEL solutions contain no antimicrobial agent. TISSEEL Fibrin Sealant is intended for single use in one patient only and unused solution remaining in the double-chamber syringe should be discarded.

Where can you get more information?

You can get more information from your doctor or pharmacist.

Name and address of the Sponsor

TISSEEL, Two component Fibrin Sealant, deep frozen, is manufactured by Baxter AG, Vienna, Austria, and supplied in Australia by:

Baxter Healthcare Pty Limited
1 Baxter Drive,
Old Toongabbie NSW 2146, Sydney

The last revision: 07 November 2011.

AUST R 147141

TISSEEL [Fibrin Sealant] is a trademark of Baxter International Inc.