

Consumer Medicine Information

TISSEEL Duo 500

*Two-Component Fibrin Sealant,
Deep-Frozen*

What is in this leaflet?

This leaflet answers some common questions about the **TISSEEL Duo 500, Two-Component Fibrin Sealant, deep frozen [TISSEEL Duo 500]**. 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 by using **TISSEEL Duo 500**.

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

What TISSEEL Duo 500 is used for?

TISSEEL Duo 500 is used to help stop excessive blood loss during surgery by inducing clotting. This clot has also sealing properties. Thus, it can also be used as an aid to help in the closure of colostomies.

How does TISSEEL Duo 500 work?

The blood coagulation factors in the composition of **TISSEEL Duo 500** are the same to those found in the normal healthy individuals. They are isolated from healthy human plasma, except aprotinin which is isolated from cow's lung (bovine). The components are packed in two separate syringes. One of the syringes contains Sealer Protein Solution while the others contain Thrombin Solution. Both syringes are stored in a deep frozen state. They will be warmed up to 37°C just prior to use.

Before you are given the TISSEEL Duo 500

TISSEEL Duo 500 should not be given to you if:

- you have a tendency for allergic reaction 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 past.

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

The use of **TISSEEL Duo 500** during your surgical operation under any of these conditions is not recommended, due to insufficient information supporting such usages. If there is a need to consider the use of this product during your 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 Duo 500 is given

How much is given:

Your surgeon will decide how much **TISSEEL Duo 500** will be given to you, which depends on your need and condition.

How it is given:

TISSEEL Duo 500 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 (data sheet).

Case of overdose

TISSEEL Duo 500 is used only for local application and thus overdose is unlikely to occur.

While you are treated with TISSEEL Duo 500

Discuss with your doctor and surgeon the progress you have experienced after the treatment, especially during the first few days after surgery. As **TISSEEL Duo 500** is given in a hospital, your healthcare professional will record your progress and any 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 known as "anaphylactic shock" may occur. In this situation, your healthcare professional will take 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 descriptions

What TISSEEL Duo 500 looks like

It is presented in a two pre-filled syringe package under deep-frozen state. Each pack of **TISSEEL Duo 500** contains accessory devices used for a simultaneous application of the contents of both syringes. They are packed under sterile conditions and presented in a deep-frozen state, at -18°C or colder.

What is in TISSEEL Duo 500?

The active components of **TISSEEL Duo 500** are plasma proteins isolated from pooled human blood of healthy donors according to WHO guidelines. The active components are filled in two separate syringes, (i) Sealer Protein Solution and (ii) Thrombin Solution, as shown in the following Table 1.

Table 1: TISSEEL Duo 500 is supplied in three different package sizes of 1.0, 2.0 and 5.0 mL, containing the following components:

	Package sizes			
Sealer Protein Solution	Active Ingredients:	1 mL	2 mL	5 mL
	as total Protein (mg)	100 - 130	200 - 260	500 - 650
	Clottable protein (human) thereof: Fibrinogen (mg)	70 - 110	140 - 220	350 - 550
	Fibronectin (mg)	2 - 9	4 - 18	10 - 45

	Package sizes			
Sealer Protein Solution	Active Ingredients:	1 mL	2 mL	5 mL
	Factor XIII, human (Unit)	10 - 50	20 - 100	50 - 250
	Aprotinin, bovine (KIU)	3000	6000	15000
	Excipients:			
	Human albumin (mg)	10 - 20	20 - 40	50 - 100
	Glycine (mg)	15 - 35	30 - 70	75 - 175
	Sodium Chloride (mg)	2 - 4	4 - 8	10 - 20
	Sodium Citrate (mg)	4 - 8	8 - 16	20 - 40
	Polysorbate 80 (mg)	0.2 - 0.4	0.4 - 0.8	1 - 2
	Creatine monohydrate (mg)	12 - 18	24 - 36	60 - 90
	Volume: w. inject. q.s. (mL)	1.0	2.0	5.0
Thrombin Solution	Active Ingredients:			
	Thrombin, human (IU)	350 - 500	700 - 1000	1750 - 2500
	Calcium Chloride (µmol)	40	80	200
	Excipients:			
	Sodium Chloride (mg)	10	20	50
	Glycine (mg)	3	6	15
	Volume: w. inject.q.s (mL)	1.0	2.0	5.0
	Combined Volume	2.0	4.0	10.0

How to store TISSEEL Duo 500

TISSEEL Duo 500 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.

The thawed solution may be used within 48 hours when stored at or below 25°C in the unopened, undamaged sterile pack. After thawing, the solution must not be refrozen or refrigerated. **TISSEEL Duo 500** solutions contain no antimicrobial agent. **TISSEEL Duo 500** is intended for single use in one patient only and unused solution remaining in the syringes 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 Duo 500, Two-component Fibrin Sealant, deep-frozen, steam treated, is manufactured by Baxter AG, Vienna, Austria.

Supplied in Australia by:
Baxter Healthcare Pty Limited
1 Baxter Drive,
Old Toongabbie
NSW 2146, Sydney

Supplied in New Zealand by:
Baxter Healthcare Limited
33 Vestey Drive
Mt Wellington
Auckland

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