TachoSil® Medicated Sponge

human fibrinogen and human thrombin

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about TachoSil. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you having TachoSil against the benefits they expect it will have for you.

If you have any concerns about receiving this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What TachoSil is used for

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

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

When the sponge 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 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.

Before you receive TachoSil

When you must not have it

Do not take TachoSil if you have an allergy to:

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

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 in not intended to be given intravascularly.

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

If you are not sure whether you should have this medicine, talk to your doctor.

Before you start to have it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

Tell your doctor if you are below 18 years of age.

There is not enough information to recommend the use of TachoSil in children below 18 years of age.

If you have not told your doctor about any of the above, tell them before you receive TachoSil.

Taking other medicines

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

Some medicines and TachoSil may interfere with each other.

How TachoSil is given

Follow all directions given to you by your doctor or pharmacist 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.

After you have received TachoSil

Things you must 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.

If you become pregnant soon after receiving TachoSil, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Side effects

Tell your doctor as soon as possible if you do not feel well after you have been given TachoSil.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor as soon as possible if you notice any of the following:

- fever
- changes in the way your heart beats.

These are the more common side effects of the medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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
- fever, drowsiness, chills and runny nose followed about two weeks later by a rash and joint pain
- pain in your abdomen or bowels

These may be serious side effects and you may need urgent medical attention. Serious side effects are rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Product description and storage

Storage

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

What it looks like

TachoSil is an off-white sponge, coloured yellow on the active side.

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

Ingredients

Each square centimetre of the sponge contains 5.5 mg human fibrinogen and 2.0 IU human thrombin as the active ingredients.

TachoSil also contains:

- equine collagen
- human albumin

- riboflavine
- sodium chloride
- sodium citrate dihydrate
- arginine hydrochloride.

Manufacturer and Supplier

Supplied in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd

Level 5

2 Chifley Square

Sydney NSW 2000

Distributed in Australia by:

Baxter Healthcare Pty Ltd

1 Baxter Drive

Old Toongabbie NSW 2146

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