EVICEL®

Solutions for Fibrin Sealant (Human Thrombin, Human Fibrinogen and Factor XIII)

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about EVICEL® Solutions for 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 by using EVICEL® Solutions for Fibrin Sealant.

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.

Read this leaflet carefully before you start using this medicine

Keep this leaflet. You may need to read it again.

What is EVICEL® and what is it used for?

EVICEL® is a Fibrin Sealant which is supplied in Australia as a package containing two separate vials, each containing 1 mL, 2 mL or 5 mL of solution Human Fibrinogen and Human Thrombin, respectively.

An application device and appropriate accessory tips are supplied separately.

EVICEL® is applied during surgical operations to reduce bleeding and oozing during and after the operation. EVICEL® is also used to seal tissues during neurosurgery. It is dripped or sprayed onto cut tissue where it forms a thin layer that seals the tissue and/or stops bleeding.

EVICEL® can also be used in blood vessel surgery, in surgery taking place in the area between the bowels and the posterior abdominal wall, and in brain surgery.

How does EVICEL® work?

Fibrinogen is a concentrate of clottable protein and thrombin is an enzyme that causes clottable protein to coalesce. Thus, when the two components are mixed together they clot instantly.

Before you are given the EVICEL®

EVICEL® should not be given to you if

- You are hypersensitive (allergic) to products made from human blood or to any of the other ingredients of EVICEL®. Signs of such reactions include hives, rash, tightness of the chest, wheezing, drop in blood pressure and breathing difficulties. If these symptoms occur, the administration has to be discontinued immediately.
- The expiry date printed on the pack has passed.

Take special care with EVICEL®

- When EVICEL® is applied during surgery, the surgeon must ensure that it is only applied onto the surface of tissue. EVICEL® must not be injected into tissue or blood vessels because it would cause clots which could be fatal.
- The use of EVICEL® has not been studied in the following procedures, and there is therefore no information to show that it would be effective in these procedures:
  - controlling bleeding in the stomach or intestines by applying the product through an endoscope (tube)
  - sealing the stomach or the bowel in order to avoid leakage of their contents after they have been sutured
  - and in spinal procedures.
- Life threatening air or gas embolism has occurred with the use of spray devices employing a pressure regulator to administer EVICEL®. This event appears to be related to the use of the spray device at higher than recommended pressures and/or in close proximity to the tissue surface. To avoid the risk of potentially life threatening air embolism EVICEL® should be sprayed using pressurised CO_2 gas only. When spraying EVICEL®, changes in blood pressure, pulse, oxygen saturation and end tidal CO_2 should be monitored because of the possibility of occurrence of air or gas embolism.
- The use of EVICEL® in patients undergoing radiotherapy within 7 days after surgery has not been evaluated. It is not known whether radiation therapy could affect the efficacy of fibrin sealant when used for suture line sealing in dura mater closure.
- Nearby areas should be protected to make sure that EVICEL® is only applied onto the surface which is to be treated.

- As with any product containing proteins, allergic type hypersensitivity reactions are possible. Signs of such reactions include hives, rash, tightness of the chest, wheezing, drop in blood pressure and anaphylaxis. If these symptoms occur, the administration has to be discontinued immediately.
- When medicines are made from human blood or plasma, certain measures are put into place to prevent infections being passed on to patients. These include careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded, and the testing of each donation and pools of plasma for signs of viruses/infections.
  Manufacturers of these products also include steps in the processing of the blood and plasma that can inactivate or remove viruses. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded.
  This also applies to any unknown or emerging viruses, or other types of infections. The measures taken in the manufacture of fibrinogen and thrombin are considered effective for lipid coated viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus, and the non-enveloped virus, hepatitis A. The measures taken may be of limited value against parvovirus B19.
  Parvovirus B19 infection may be serious for pregnant women (foetal infection) and for individuals whose immune system is depressed or who have some types of anaemia (e.g. sickle cell disease or haemolytic anaemia).
  The healthcare professionals will record the name and batch number(s) of EVICEL® used in order to trace any possible infection source.

You must tell your doctor if you

- are taking or have recently taken any other medicines, even those not prescribed.
- You must tell your doctor, if you are pregnant, planning to become pregnant or breast feeding.
  There is not enough information available to know whether any particular risks are associated with the use of EVICEL® during pregnancy or whilst breast-feeding. However, since EVICEL® is used during a surgical operation, if you are pregnant or breast-feeding you should discuss the overall risks of the operation with your doctor.

Use in Children

Data is too limited to support the safety and effectiveness of EVICEL® in children.

How EVICEL® is given

The doctor treating you will administer EVICEL® during surgery.

During your operation, your doctor will drip or spray EVICEL® onto raw tissue, using an application device. This device allows equal amounts of the two components of EVICEL® to be administered at the same time, and ensures that they mix evenly, which is important for the sealant to have its optimal effect.

The amount of EVICEL® that will be applied depends on the surface area of tissue to be treated during the operation. It will be dripped onto the tissue in short bursts or sprayed in very small amounts (0.1-0.2 mL), to produce a thin, even layer. If application of a single layer of EVICEL® does not completely stop the bleeding, a second layer may be applied.

Case of overdose

No case of overdose has been reported.

Side effects

Like all medicines, EVICEL® can have side effects, although not everybody gets them.

EVICEL® is a fibrin sealant. Fibrin sealants in general may, in rare cases (may affect up to 1 in 1,000 people), cause an allergic reaction. If you experience an allergic reaction you might have one or more of the following symptoms: skin rash, hives or wheals (nettlerash), tightness of the chest, chills, flushing, headache, low blood pressure, lethargy, nausea, restlessness, increased heart rate, tingling, vomiting, or wheezing. No allergic reactions have so far been reported in patients treated with EVICEL®.

There is also a theoretical possibility that you could develop antibodies to the proteins in EVICEL®, which could potentially interfere with blood clotting.

If you feel unwell tell your doctor immediately, even if your symptoms are different from those just described.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

In clinical studies with EVICEL® some undesired events occurred for which causal relation to the application of EVICEL® could not be excluded.

Most serious side effects

- Watery fluid coming out of your wound or nose (CSF leakage/CSF rhinorrhea)
- Headache, nausea, and vomiting (due to Subdural Hygroma, which is accumulation of CSF in the subdural space)
- Fever, or prolonged constipation, flatulence (due to abdominal abscess)

The frequency of the effects listed above was common (may affect up to 1 in 10 people).

- Numbness or pain in your extremities, change in skin colour (due to Graft Occlusion or Thrombosis)

The frequency of this effect was uncommon (may affect up to 1 in 100 people).

Other side effects

Other side effects which were reported to be common during clinical trials with EVICEL® (i.e., may affect up to 1 in 10 people) included meningitis, fever, difficulties with blood clotting and accumulation of CSF fluid in the brain cavities (hydrocephalus). The frequency of all of these effects was common.

Side effects which were uncommon during clinical trials with EVICEL® (i.e., may affect up to 1 in 100 people) included infection, blood accumulation (haematoma), swelling, decreased haemoglobin, and post-operative wound complications (including bleeding or infection).

Product Description

What is in EVICEL®?

The active ingredients are as follows:

- Component 1: Fibrinogen - human (50 - 90 mg/mL clottable protein)
- Component 2: Thrombin - human (800 - 1200 IU/mL)

Other ingredients are:

- Component 1: arginine hydrochloride, glycine, sodium chloride, sodium citrate, calcium chloride and water for injections.
- Component 2: calcium chloride, human albumin, mannitol, sodium acetate and water for injections.

EVICEL® in Australia is available in the following sizes: 2 mL (2 x 1 mL vials), 4 mL (2 x 2 mL vials) and 10 mL (2 x 5 mL).

What EVICEL® looks like and contents of the pack

EVICEL® is a Human Fibrin Sealant which is supplied in Australia as a package containing two separate vials, each containing 1 mL, 2 mL or 5 mL solution of Human Fibrinogen and Human Thrombin, respectively.

An application device and appropriate accessory tips are supplied separately. Fibrinogen and Thrombin are packaged together as two vials each containing the same volume (1 mL, 2 mL or 5 mL in Australia) of frozen, sterile solution, which is colourless or yellowish when thawed. Fibrinogen is a concentrate of clottable protein and Thrombin is an enzyme that causes clottable protein to coalesce. Thus, when the two components are mixed together they clot instantly.

How to store EVICEL®

Keep out of the reach and sight of children.

The vials must be stored in an upright position. Store in freezer at or below - 18°C.

Do not use EVICEL® after the expiry date which is stated on the label as well as on the carton after EXP. The expiry date refers to the last day of that month.

Keep the vials in the outer carton in order to protect from light. After thawing, unopened vials can be stored at 2-8°C and protected from light, for up to 30 days. Do not refreeze.

The Fibrinogen and Thrombin components are stable at room temperature for up to 24 hours but once drawn up into the application device, they must be used immediately.

Where can you get more information?

You can get more information from your doctor or pharmacist.

Name and Address of Sponsor:

Johnson & Johnson Medical Pty Ltd.
1-5 Khartoum Rd, North Ryde
NSW 2113, AUSTRALIA

Manufacturer:

Omrix Biopharmaceuticals Ltd.
MDA Blood Bank, Sheba Hospital,
Ramat Gan, POB 888,
Kiryat Ono 5510801, ISRAEL

Poison schedule of the medicine

Exempt from scheduling

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