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EPAR summary for the public

Evicel

human clottable protein / human thrombin

This is a summary of the European public assessment report (EPAR) for Evicel. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Evicel.

What is Evicel?

Evicel is a medicine that is used as a sealant (glue). It is available as two solutions, one containing the active substance human clottable protein (50 to 90 mg/ml), and the other containing the active substance human thrombin (800 to 1200 international units per millilitre).

What is Evicel used for?

Evicel is used by surgeons to help reduce local bleeding during operations when standard techniques are not sufficient. It can also be used in addition to sutures (stitching) during vascular surgery (surgery on the blood vessels).

Evicel can also be used in addition to sutures to obtain a watertight closure of the dura mater (a thin fluid-filled membrane surrounding the brain and the spinal cord) during brain surgery.

The medicine can only be obtained with a prescription.

How is Evicel used?

Evicel should only be used by an experienced surgeon who has been trained in the use of Evicel. Before use, the two solutions of Evicel are mixed together using a special device that is supplied with the medicine. Evicel is then dripped or sprayed on the surface of the wound until it forms a thin layer. The volume of Evicel to be used depends on a number of factors, including the type of surgery, the size of the wound and the number of applications.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

How does Evicel work?

The active substances in Evicel, human clottable protein and thrombin, are natural substances obtained from human plasma (the liquid part of the blood). The human clottable protein contains as its main component, fibrinogen, a protein involved in the natural clotting process.

When the two active substances are mixed together, thrombin cuts fibrinogen up into smaller units called fibrin. The fibrin then aggregates (sticks together) and forms a fibrin clot that helps the wound to heal, preventing bleeding.

How has Evicel been studied?

Because the thrombin solution of Evicel is also used in another medicine, Quixil, the company used some data from Quixil to support the use of Evicel.

Evicel has been studied in two main studies involving a total of 282 patients. The first study compared Evicel with manual compression (applying direct pressure) in reducing bleeding during vascular surgery. The main measure of effectiveness was the number of patients with no bleeding (haemostasis) at the site of application, four minutes after having received Evicel or manual compression. The second study compared Evicel with Surgicel (a material used to help control bleeding) in reducing bleeding during abdominal surgery (surgery of organs in the tummy). The main measure of effectiveness was the number of patients with no bleeding at the site of application, 10 minutes after having received Evicel or Surgicel.

Evicel has also been studied in one further main study involving 139 patients undergoing brain surgery and whose dura mater was leaking fluid following suturing of the dural incision. The study compared the effectiveness of Evicel in addition to sutures with sutures alone in sealing the dura mater. The main measure of effectiveness was the number of patients whose dura mater closure was watertight with no leakage.

What benefit has Evicel shown during the studies?

Evicel was more effective than the comparator treatments in reducing the bleeding at the site of application. In vascular surgery, 85% of the patients had no bleeding four minutes after treatment with Evicel (64 out of 75), compared with 39% of the patients treated with manual compression (28 out of 72). During abdominal surgery, 95% of the patients had no bleeding 10 minutes after treatment with Evicel (63 out of 66), compared with 81% of the patients treated with Surgicel (56 out of 69).

In dura mater closure, 92% of patients treated with Evicel (82 out of 89) had a watertight closure compared with 38% of the patients who did not receive Evicel (19 out of 50).

What is the risk associated with Evicel?

As for other sealants, Evicel may cause an allergic reaction which can be severe especially when Evicel is used repeatedly. In rare cases, patients may also develop antibodies to the proteins in Evicel, which could interfere with blood clotting. Thromboembolic complications (blood clots) may occur if Evicel is unintentionally injected into a blood vessel. Cases of gas embolism (gas bubbles in the blood that affect the blood flow) have occurred when Evicel was applied as spray. For the full list of all side effects reported with Evicel, see the package leaflet.

Evicel must not be used in people who are hypersensitive (allergic) to human clottable protein, thrombin or any of the other ingredients. It must not be given as an injection into a blood vessel. When used in endoscopic procedures (procedures that use an endoscope for viewing internal organs),

Evicel must not be applied as a spray. Evicel must also not be used in dura mater closure if the dura mater cannot be sutured, or if there are gaps greater than 2 mm after suturing. Evicel must also not be used as a glue for the fixation of dural patches (material which is sewn over an opening in the dura mater).

For further details see the package leaflet.

Why has Evicel been approved?

The CHMP decided that Evicel's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe use of Evicel?

In order to reduce the risk of gas embolism with spray application, the company will provide educational material and training to all surgeons who will use Evicel as a spray. In addition, the company will ensure that Evicel is used with pressure regulators that do not exceed the maximum pressure required to deliver the fibrin sealant, and that the regulators contain labels stating the recommended pressure and distance for the spray application.

Other information about Evicel

The European Commission granted a marketing authorisation valid throughout the European Union for Evicel on 6 October 2008.

The full EPAR for Evicel can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Evicel, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2013.