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EPAR summary for the public

Evarrest

fibrinogen / thrombin

This is a summary of the European public assessment report (EPAR) for Evarrest. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Evarrest.

For practical information about using Evarrest, patients should read the package leaflet or contact their doctor or pharmacist.

What is Evarrest and what is it used for?

Evarrest is a surgical product used in adults to help stop bleeding during surgery when standard methods for controlling bleeding are not sufficient. It is made of absorbable material coated on one side with two active substances, fibrinogen and thrombin, and is available as 10.2 cm x 10.2 cm patches. During surgery, the patches are cut to shape and size and used to seal off the bleeding area.

How is Evarrest used?

Evarrest should only be used by experienced surgeons who will judge the amount to use based on the size and location of the bleeding area. It should only be used in a single layer with an overlap of 1 to 2 cm on the surrounding non-bleeding tissue.

Evarrest is made of absorbable material that can be left in the patients after surgery. The material is absorbed by the body in around 8 weeks. However no more than two patches should be left in the patient as there has not been enough experience with larger quantities.

How does Evarrest work?

The active substances in Evarrest, fibrinogen and thrombin, are proteins extracted from the blood, which are involved in the natural clotting process. Thrombin works by cutting fibrinogen up into smaller units called fibrin, which then stick together to form clots.

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When an Evarrest patch is applied to a bleeding area during surgery, the moisture causes the active substances to react together, leading to the rapid formation of clots. The clots enable the patch to stick more firmly to the tissue thereby helping to stop the bleeding.

What benefits of Evarrest have been shown in studies?

Evarrest has been shown in studies to be effective in helping to stop bleeding during surgeries, with most patients having their bleeding stopped within 4 minutes.

One study compared Evarrest with another product, Surgicel, in patients undergoing abdominal, thoracic and pelvic surgeries. 98% of the patients in the Evarrest group (59 out of 60) had their bleeding stopped within 4 minutes (with no recurrence of bleeding during a 6-minute observation period) compared with 53% of patients in the Surgicel group (16 out of 30).

Two studies compared Evarrest with commonly used surgical techniques considered to be standard care. In a study in patients undergoing abdominal, thoracic and pelvic surgeries, 84% of patients in the Evarrest group had their bleeding stopped within 4 minutes (50 out of 59) compared with 31% (10 out of 32) in the standard care group. Similar results were seen in a study in patients undergoing liver surgery: 83% of patients in the Evarrest group (33 out of 40) had their bleeding stopped within 4 minutes compared with 30% of the standard care group (13 out of 44).

What are the risks associated with Evarrest?

The complications that arise in patients being treated with Evarrest are generally related to the surgical procedure and the underlying conditions, and include post-surgery bleeding and increased fibrinogen levels in the blood. For the full list of all side effects reported with Evarrest, see the package leaflet.

Evarrest must not be used to repair the walls of large blood vessels, must not be applied to the inside of blood vessels and must not be used in closed spaces (such as openings in bones). It must also not be used in patients with active infection or in contaminated areas.

Why is Evarrest approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that Evarrest was shown to be effective when used to stop bleeding in surgery and the product could be a suitable alternative to other products and techniques. The complications seen in studies with Evarrest were generally related the surgical procedure and the underlying conditions although there were cases of re-bleeding from the sites where Evarrest patches were used. Evarrest should therefore only be used when standard methods for controlling bleeding are not sufficient.

The CHMP concluded that the benefits of Evarrest outweigh its risks and recommended that it be granted marketing authorisation.

What measures are being taken to ensure the safe and effective use of Evarrest?

A risk management plan has been developed to ensure that Evarrest is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Evarrest, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Evarrest

The European Commission granted a marketing authorisation valid throughout the European Union for Evarrest on 25 September 2013.

The full EPAR for Evarrest 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 Evarrest, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2013.