EMA/580809/2023
EMEA/H/C/004446

VeraSeal (*human fibrinogen / human thrombin*)

An overview of VeraSeal and why it is authorised in the EU

What is VeraSeal and what is it used for?

VeraSeal is a sealant (glue) used to stop bleeding during surgery or to support stitches during surgery on blood vessels.

VeraSeal is used when standard surgical techniques do not work well enough. It contains the active substances human fibrinogen and human thrombin.

How is VeraSeal used?

VeraSeal should only be used by an experienced surgeon who has been trained in its use. It is available as two prefilled syringes in a syringe holder, one containing a solution of human fibrinogen, and the other containing a solution of human thrombin. Before use, the syringes are attached to a device supplied with the medicine that allows their contents to mix as they are dripped or sprayed on the wound. The amount of VeraSeal to be used depends on a number of factors, including the type of surgery, the size of the wound and the number of applications.

How does VeraSeal work?

The active substances in VeraSeal, fibrinogen and thrombin, are proteins present in human plasma (the liquid part of the blood), which are involved in the blood clotting process.

When the two active substances are mixed, thrombin cuts fibrinogen up into fibrin (protein involved in forming blood clots in the body). The fibrin then aggregates (sticks together) and forms a fibrin clot that helps the wound to heal, preventing bleeding.

What benefits of VeraSeal have been shown in studies?

Three main studies in 614 patients, mainly adults, found that VeraSeal is effective at stopping bleeding within 4 minutes of applying it during surgery.

In one study of blood vessel surgery, VeraSeal worked better than manual compression, with 76% of patients having no bleeding 4 minutes after treatment with VeraSeal (83 out of 109), compared with 23% after manual compression (13 out of 57).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

In a second study of organ surgery, VeraSeal was as effective as another product Surgicel: 93% of the patients had no bleeding 4 minutes after treatment with VeraSeal (103 out of 111), while 81% of the patients had no bleeding with Surgicel (91 out of 113).

In a third study of soft tissue surgery, VeraSeal was as effective as Surgicel: 83% of the patients had no bleeding 4 minutes after treatment with VeraSeal (96 out of 116), compared with 78% of the patients after treatment with Surgicel (84 out of 108).

A fourth study was carried out in 178 children and adolescents who received either VeraSeal or another medicine containing fibrinogen and thrombin (Evicel) to stop bleeding during surgery. In this study, 97% (88 out of 91) of patients given VeraSeal had no bleeding 4 minutes after treatment and no new bleeding requiring treatment until the end of the surgery, compared with 95% (83 out of 87) of patients given Evicel.

What are the risks associated with VeraSeal?

For the full list of side effects and restrictions with VeraSeal, see the package leaflet.

The most common side effects with VeraSeal (which may affect up to 1 in 10 people) include nausea (feeling sick), pruritus (itchiness) and procedural pain (pain from the surgery). Rarely, VeraSeal may cause an allergic reaction which can be severe especially when the medicine is used repeatedly. In rare cases, patients may develop antibodies to the proteins in VeraSeal, which could interfere with blood clotting. Thromboembolic complications (blood clots) may occur if VeraSeal is accidentally injected into a blood vessel.

VeraSeal must not be used intravascularly (inside blood vessels) or to treat heavy bleeding of the arteries.

Why is VeraSeal authorised in the EU?

VeraSeal has been shown to effectively stop bleeding during surgery, which can be expected to reduce blood loss, reduce time in the operating theatre and possibly shorten hospital stays. Although patients could develop antibodies against the medicine, which might reduce its effectiveness, this has not been seen in the studies.

The observed side effects were as expected with major surgeries or the patient's condition. The European Medicines Agency therefore decided that VeraSeal's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of VeraSeal have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of VeraSeal are continuously monitored. Side effects reported with VeraSeal are carefully evaluated and any necessary action taken to protect patients.

Other information about VeraSeal

VeraSeal received a marketing authorisation valid throughout the EU on 10 November 2017.

Further information on VeraSeal can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/veraseal

This overview was last updated in 01-2024.