EMA/620652/2017
EMEA/H/C/004446

EPAR summary for the public

VeraSeal

human fibrinogen / human thrombin

This is a summary of the European public assessment report (EPAR) for VeraSeal. 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 VeraSeal.

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

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 surgery 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 (80 mg/ml), and the other containing a solution of human thrombin (500 international units/ml). 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 substances present in human plasma (the liquid part of the blood), which are involved in the normal blood clotting process.

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When the two active substances are mixed, thrombin cuts fibrinogen up into fibrin. 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 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).

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).

Finally, 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).

What are the risks associated with VeraSeal?

The most common side effects with VeraSeal (which may affect up to 1 in 10 people) are 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 have developed 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. Cases of gas embolism (gas bubbles that block blood flow) have occurred when such sealants were applied as spray.

VeraSeal must not be used intravascularly (inside blood vessels) or to treat heavy bleeding of the arteries. VeraSeal must not be applied by spraying during endoscopy (a procedure that uses a tube for viewing inside the body).

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

Why is VeraSeal approved?

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.

As for all medicines obtained from blood, infections could be transmitted with the medicine; however, the medicine is manufactured using filtration and a process to inactivate viruses that minimise this risk. 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 recommended that it be approved for use in the EU.

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

The company that markets VeraSeal will provide educational materials for healthcare professionals with information on how to use the medicine safely when it is applied by spraying.

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

Other information about VeraSeal

The European Commission granted a marketing authorisation valid throughout the European Union for VeraSeal on 10 November 2017.

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

This summary was last updated in 11-2017.