

VeraSeal™ Solutions for sealant (human fibrinogen/human thrombin) Abbreviated Prescribing Information (API)

Please read Summary of Product Characteristics (SmPC) for full product information before prescribing.

Composition

Component 1: Human fibrinogen 80 mg/ml

Component 2: Human thrombin 500 IU/ml

Therapeutic Indications:

VeraSeal™ is indicated as supportive treatment in adults where standard surgical techniques are insufficient:

- for improvement of haemostasis.
- as suture support in vascular surgery.

CONTRAINDICATIONS

VeraSeal™ must not be applied intravascularly.

Hypersensitivity to the active substance or to any of the excipients listed in SmPC.

VeraSeal™ must not be used for the treatment of severe or brisk arterial bleeding.

Spray application of VeraSeal must not be used in endoscopic (intraluminal) procedures.

This medicinal product must not be mixed with other medicinal products.

Posology & administration

The use of VeraSeal™ is restricted to experienced surgeons who have been trained in the use of this medicinal product.

The volume of VeraSeal to be applied and the frequency of application should always be oriented towards the underlying clinical needs for the patient. The initial volume of the product to be applied at a chosen anatomic site or target surface area should be sufficient to entirely cover the intended application area. The application can be repeated, if necessary. The safety and efficacy of VeraSeal in children aged 0 to 18 years has not yet been established.

WARNINGS AND PRECAUTIONS

For episessional use only.

Life threatening thromboembolic complications may occur if the preparation is unintentionally applied intravascularly.

VeraSeal™ spray application should only be used if it is possible to accurately judge the spray distance, especially during laparoscopy.

When using accessory tips, the instructions for use of the tips should be followed.

Before administration of VeraSeal, care must be taken that the parts of the body outside the desired application area are sufficiently protected (covered) to prevent tissue adhesion at undesired sites.

VeraSeal should be applied as a thin layer. Excessive clot thickness may negatively interfere with the product's efficacy and the wound healing process.

As with any protein product, allergic type hypersensitivity reactions are possible.

When medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

Undesirable effects

Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the application site, bronchospasm, chills, flushing, generalized urticaria, headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia, tightness of the chest, tingling, vomiting, wheezing) may occur in rare cases in patients treated with fibrin sealant/haemostatic products. In isolated cases, these reactions have progressed to severe anaphylaxis. Such reactions may especially be seen, if the preparation is applied repeatedly, or administered to patients known to be hypersensitive to constituents of the product. Antibodies against components of fibrin sealant/haemostatic products may occur rarely. Inadvertent intravascular injection could lead to thromboembolic event and disseminated intravascular coagulation (DIC), and there is also a risk of anaphylactic reaction (Please refer to full SmPC). For safety information with respect to transmissible agents, please refer to full SmPC. The most common adverse reactions (frequencies of $\geq 1/100$ to $< 1/10$) were nausea, procedural pain and pruritus.

Pregnancy and Breast Feeding

The safety of fibrin sealant/haemostatic products for use in human pregnancy or breast-feeding has not been established in controlled clinical trials. Therefore, the product should be administered to pregnant and breast-feeding women only if clearly needed.

SUPPLY CLASSIFICATION:

M/Medicinal product (biologic) subject to restricted medical prescription.

MA HOLDER: Instituto Grifols, S.A., Can Guasc, 2 - Paret del Vallès, E-08150 Barcelona, Spain

MA NUMBER(S):

EEU/1/17/1239/001 2 ml, EEU/1/17/1239/002 4 ml, EEU/1/17/1239/003 6 ml, EEU/1/17/1239/004 10 ml

DATE OF PREPARATION: September 2020

PHARMACOVIGILANCE:

Adverse events should be reported via the appropriate national reporting system. Adverse events should also be reported to Instituto Grifols, S.A. by Email: gds@grifols.com

Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.

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