ARTISS
[Solutions for Sealant]

ARTISS Product Preparation - Quick Reference Guide

Thawing **A** in **sterile water bath**

thawing times
at 33-37°C
(without pouch)

2 ml – 5 min

4 ml – 5 min

10 ml – 12 min

Thawing **B** with **incubator**

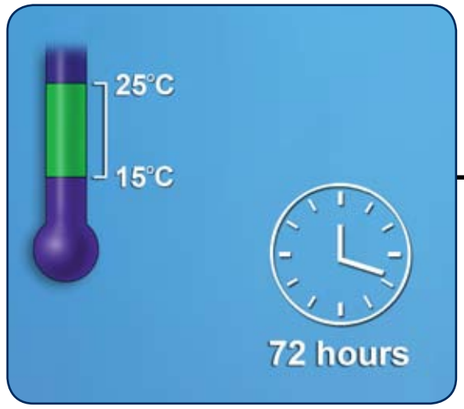
thawing times
at 33-37°C
(with sterile pouch)

2 ml – 40 min

4 ml – 85 min

10 ml – 105 min

Thawing **C** at **room temperature** + **warming**



- thaw at room temperature
- interim storage max. 14 days

or

warming A

2 ml – 5 min
4 ml – 5 min
10 ml – 12 min

warming B

2 ml – 15 min
4 ml – 25 min
10 ml – 35 min

DO NOT

- heat above 37°C
- microwave
- thaw the product by holding it in your hands
- remove cap before use
- refrigerate
- refreeze
- use for more than 4 hours after warming to 37°C
- use at room temperature without warming to 37°C

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This abbreviated summary of product characteristics (SmPC) is intended for international use. Please note that it may differ from the licensed SmPC in the country where you are practicing.

Therefore, please always consult your country-specific SmPC or package leaflet.

ARTISS, Solutions for Sealant, deep frozen

COMPOSITION: ARTISS consists of: • Human Fibrinogen (as clottable protein) 91 mg1/ml • Synthetic Aprotinin 3000 KIU2/ml • Human Thrombin 4 IU3/ml • Calcium Chloride 40 µmol/ml

INDICATIONS: ARTISS is indicated as tissue glue to adhere/seal subcutaneous tissue in plastic, reconstructive and burn surgery, as replacements or adjuncts to sutures or staples. In addition, ARTISS is indicated as adjunct to hemostasis on subcutaneous tissue surfaces.

CONTRAINDICATIONS: ARTISS is not indicated to replace skin sutures intended to close surgical wound. ARTISS alone is not indicated for the treatment of massive and brisk arterial or venous bleeding. ARTISS can never be applied intravascularly. Hypersensitivity to the active substances or to any of the excipients.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE: For epilesional use only. Do not apply intravascularly. Life threatening thromboembolic complications may occur if the preparation is unintentionally applied intravascularly. Soft tissue injection of ARTISS carries the risk of local tissue damage.

ARTISS is not indicated for hemostasis and sealing in situations where a fast clotting of the sealant is required. Especially in cardiovascular procedures in which sealing of vascular anastomoses is intended ARTISS should not be used. ARTISS is not indicated for use in neurosurgery and as a suture support for gastrointestinal anastomoses or vascular anastomoses as no data are available to support these indications. ARTISS should only be applied as a thin layer. Excessive clot thickness may negatively interfere with the product's efficacy and the wound healing process.

Before administration of ARTISS, care is to be taken that parts of the body outside the designated application area are sufficiently protected/covered to prevent tissue adhesion at undesired sites.

As with any protein-containing product, allergic type hypersensitivity reactions are possible. Signs of hypersensitivity reactions may include hives, generalized urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis. If these symptoms occur, the administration must be discontinued immediately.

ARTISS contains synthetic aprotinin. Even in case of strict local application, there is a risk of anaphylactic reaction linked to the presence of aprotinin. The risk seems to be higher in cases where there was previous exposure, even if it was well tolerated. Therefore any use of aprotinin or aprotinin containing products should be recorded in the patients' records.

In the event of anaphylactic or severe hypersensitivity reactions, administration is to be discontinued and state-of-the-art emergency measures are to be taken. In case of shock, standard medical treatment for shock should be implemented.

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Baxter

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Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, 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 or other pathogens. The measures taken are considered effective for enveloped viruses such as HIV, HBV, and HCV, and for the non-enveloped virus HAV. The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (fetal infection) and for individuals with immunodeficiency or increased erythropoiesis (e.g., hemolytic anemia).

UNDESIRABLE EFFECTS: Inadvertent intravascular injection could lead to thromboembolic events and DIC and there is also a risk of anaphylactic reactions. Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the application site, bradycardia, bronchospasm, chills, dyspnoea, flushing, generalized urticaria, headache, hives, hypotension, lethargy, nausea, pruritus, restlessness, tachycardia, tightness of the chest, tingling, vomiting, wheezing) may occur in rare cases in patients treated with fibrin sealants/hemostatics. 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 aprotinin or any other constituents of the product.

Even if a first treatment with ARTISS is well tolerated, a subsequent administration of ARTISS or systemic administration of aprotinin may result in severe anaphylactic reactions. Antibodies against components of fibrin sealant may rarely occur. Adverse reactions reported from clinical studies as well as from postmarketing surveillance are summarized in the following. Known frequencies of these adverse reactions are based on a controlled clinical study in 138 patients where skin grafts were fixed to excised burn wounds using ARTISS. None of the events were classified as serious. Unknown frequencies are based on spontaneous reports from postmarketing surveillance of Baxter's fibrin sealants.

The ADRs and their frequencies are: Common (≥1/100 to <1/10): pruritus, skin graft failure; Uncommon (≥1/1000 to <1/100): dermal cyst; Unknown (cannot be estimated from the available data): anaphylactic responses, hypersensitivity, : bradycardia, tachycardia, hypotension, haematoma, dyspnoea, nausea, urticaria, flushing, impaired healing, oedema, pyrexia, seroma.

For the Posology, incompatibilities and interactions, please refer to your locally approved full SmPC.

Medicinal products are subject to medical subscription

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