PRESCRIBING INFORMATION – ARTISS

Please consult the Summary of Product Characteristics before prescribing

Name and composition: ARTISS Solutions for Sealant – one prefilled double chamber syringe containing Sealer Protein Solution (with aprotinin) deep frozen in one chamber and Thrombin Solution (with calcium chloride dihydrate) deep frozen in the other chamber. Sealer Protein Solution contains 91mg/ml human fibrinogen (clottable protein) and 3000 KIU/ml aprotinin. Thrombin Solution contains 4 IU/ml human thrombin and 40µmol/ml calcium chloride dihydrate. Presentations of 1, 2 or 5ml in each chamber resulting in total volume of 2ml, 4ml or 10ml of total volume of product ready for use. Contains human factor XIII co-purified with human fibrinogen in a range of 0.6 – 5 IU/ml.

Indication: Hospital use only. A tissue glue to adhere / seal subcutaneous tissue in plastic, reconstructive and burn surgery, replacement or adjunct to sutures or staples. Adjunct to haemostasis on subcutaneous tissue surfaces. Dosage and Route: The use of ARTISS is restricted to experienced surgeons who have been trained in the use of ARTISS. For epilesional use, do not inject. Subcutaneous use only, not recommended for laparoscopic surgery. Dose individualised and governed by indication, application methods and number of applications. Guide – 1 pack ARTISS 2ml sufficient for an area at least 10 cm2. Avoid excess granulation by applying only a thin layer. Surface of the wound should be as dry as possible.

Side effects: See summary of product characteristics for detail. Risk of anaphylactic reaction. Intravascular injection may lead to life-threatening thromboembolic events and DIC. Hypersensitivity or allergic reactions in isolated cases these reactions have progressed to severe anaphylaxis. Other known adverse reactions include dermal cyst, pruritus, skin graft failure, air or gas embolism when applied using pressurised air or gas, bradycardia, tachycardia, hypotension, haematoma, dyspnoea, nausea, urticarial, flushing, impaired healing, oedema, pyrexia and seroma.

Precautions: Caution applying ARTISS using pressurised gas, not to be used with Easy Spray / Spray Set system in enclosed body areas. Any application of pressurised air or gas is associated with a potential risk of air or gas embolism, tissue rupture or gas entrapment with compression, which may be life threatening or fatal. Use spray device pressure within manufacturers recommended range, not exceeding 2.0 bars. Do not spray closer than 10-15 cm from tissue surface. Monitor blood pressure, pulse, oxygen saturation, end tidal CO2 for possibility of occurrence of air or gas embolism. Not indicated for use where a fast clotting sealant is required, especially in cardiovascular surgery. Not for use in neurosurgery and as a suture support for gastrointestinal or vascular anastomoses. Excessive clot thickness may interfere with efficacy and wound healing. Care to prevent adhesion at undesired sites. Signs of hypersensitivity include hives, urticaria, tightness of chest, wheezing, hypotension, anaphylaxis. Risk of anaphylaxis increased if previous exposure to aprotinin. In event of hypersensitivity or anaphylaxis discontinue use and remove polymerised product from surgical site. Oxycellulose containing preparations may reduce ARTISS efficacy. Infectious diseases due to transmission of infective agents cannot be totally excluded. Use of ARTISS and batch number should be recorded in patients' notes. Carefully evaluate in patients with allergies to bovine proteins. The effects of ARTISS on fertility have not been established.

Contra-indications: Not indicated to replace sutures intended to close surgical wound. Not for treatment of massive and brisk arterial or venous bleeding. Not for intravascular use. Hypersensitivity to active substances or excipients. Spray application should not be used in endoscopic procedures. Interactions: Avoid solutions containing alcohol, iodine and heavy metals. Overdose: No cases of overdose have been reported. Legal Category: POM. **Marketing Authorisation Number** and Holder: PA2299/026/001, Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands. Date of Preparation: July 2021

IE-AS11-210005 July 2021