

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states

Artiss and associated names; Tisseel and associated names; Tissucol and associated names

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Austria	Baxter AG Industriestraße 67 1221 Vienna Austria	ARTISS – Lösungen für einen Gewebekleber	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use
Austria	Baxter AG Industriestraße 67 1221 Vienna Austria	ARTISS LYO – Pulver und Lösungsmittel für einen Gewebekleber	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIE/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Epileisional use
Austria	Baxter AG Industriestraße 67 1221 Vienna Austria	Tisseel - Lösungen für einen Gewebekleber	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use
Austria	Baxter AG Industriestraße 67 1221 Vienna Austria	Tisseel Lyo - Pulver und Lösungsmittel für einen Gewebekleber	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Epileisional use
Belgium	Baxter SA Boulevard René Branquart 80 7860 Lessines Belgium	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use
Belgium	Baxter AG Industriestraße 67 1221 Vienna Austria	Tissucol Duo 500	Syringe TISSUCOL-APROTININ: Total Proteins 100-130 mg/ml; clottable protein 75-115 mg/ml, of which fibrinogen 70-110 mg/ml and plasmatic fibronectin 2-9 mg/ml: Factor XIII 10-50 UI/ml; Plasminogen 0.04-0.12 mg/ml; Aprotinin 3000 UIK/ml (1.67 UPE/ml); Syringe THROMBIN-CALCIUM CHLORIDE: Proteins 50mg/ml; Thrombin 500 UI/ml; calcium chloride 40 µmol/ml	Solution for sealant	Epileisional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Belgium	Baxter AG Industriestraße 67 1221 Vienna Austria	Tissucol Kit	Bottle 1: Total Proteins 100-130 mg/ml; dont clottable protein 75-115 mg/ml, Factor XIII 10-50 UI/ml; Plasminogen 0.04-0.12 mg/ml; Bottle 2: Aprotinin bovine 3000 UIK/ml (1.67 UPE/ml); Bottle 3: Human Thrombin 500 IU/ml; Proteins 50mg/ml; Bottle 4: Human Thrombin 4 UI/ml; Proteins 50mg/ml; Bottle 5: calcium chloride 40 µmol/ml	Powder and solvent for sealant	Epileisional use
Belgium	Baxter AG Industriestraße 67 1221 Vienna Austria	Tissucol S/D	Human fibrinogen (clottable protein): 72-110 mg/ml Factor XIII ≤ 10 UI/ml Aprotinin: 3000 UIK/ml Human Thrombin: 500 UI/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use
Belgium	Baxter AG Industriestraße 67 1221 Vienna Austria	Tissucol S/D Kit	Human fibrinogen (clottable protein): 72-110 mg/ml Factor XIII ≤ 10 UI/ml Aprotinin: 3000 UIK/ml Human Thrombin: 500 UI/ml Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Epileisional use
Bulgaria	Baxter d.o.o. Zelezna cesta 18 1000 Ljubljana Slovenia	Artiss solution for sealant frozen	Human fibrinogen 91 mg/ml Aprotinin 3000 KIU/ml Human Thrombin 4 IU/ml Calcium Chloride 40 µmol/ml	Solution for sealant	Epileisional use
Bulgaria	Baxter d.o.o. Zelezna cesta 18 1000 Ljubljana Slovenia	Tisseel Lyo powders and solvents for sealant	Human fibrinogen 91 mg/ml Aprotinin 3000 KIU/ml Human Thrombin 4 IU/ml Calcium Chloride 40 µmol/ml	Powder and solvent for sealant	Epileisional use
Bulgaria	Baxter d.o.o. Zelezna cesta 18 1000 Ljubljana Slovenia	Tisseel solutions for sealant	Human fibrinogen 72-110 mg/ml Aprotinin 3000 KIU/ml Human Thrombin 500 IU/ml Calcium Chloride 40 µmol/ml	Solution for sealant	Epileisional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Czech Republic	Baxter Czech spol. s r.o. Karla Engliš 3201/6 150 00 Praha 5 Czech Republic	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Czech Republic	Baxter Czech spol. s r.o. Karla Engliš 3201/6 150 00 Praha 5 Czech Republic	Tisseel	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Czech Republic	Baxter Czech spol. s r.o. Karla Engliš 3201/6 150 00 Praha 5 Czech Republic	Tisseel Lyo	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Epilesional use
Denmark	Baxter A/S Gydevang 43 DK-3450 Allerød Denmark	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Intralesional use
Denmark	Baxter AG Industriestraße 67 1221 Vienna Austria	Tisseel Duo Quick	Fibrinogen 90mg/ml Fibronectin 6mg/ml Aprotinin 3000KIE/ml Coagulation Factor XIII 30IE/ml Plasminogen 80 µg/ml Thrombin human 500 IE/ml Calcium Chloride Dihydrate 40 µg/ml	Solution for sealant	Intralesional use
Denmark	Baxter A/S Gydevang 43 DK-3450 Allerød Denmark	Tissel	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Intralesional use
Finland	Baxter Oy, PL 119, 00181 Helsinki Finland	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Topical

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Finland	Baxter AG Industriestraße 67 1221 Vienna Austria	Tisseel	Fibrinogen 72-110 mg/ml Factor XIII coagulationis humanus 10 IU/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Topical
Finland	Baxter AG Industriestraße 67 1221 Vienna Austria	Tisseel duo quick	Plasmaproteinum humanum 100-130 mg/ml: Fibrinogen 90mg/ml Plasmafibrinonectinum 5,5mg/ml Factor XIII coagulationis humanus 30 IU/ml Aprotinin 1,67 Ph.Eur.U./ml Coagulation Factor XIII 30IE/ml Plasminogen 80 µg/ml Thrombin human 500 IE/ml plasmaproteinum humanum 50mg/ml Calcium Chloride Dihydrate 40 µg/ml	Solution for sealant	Topical
France	BAXTER SAS 6 Avenue Louis Pasteur 78310 MAUREPAS FRANCE	ARTISS solution for sealant	Fibrinogen 91 mg/ml Aprotinin: 3000 KIE/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use
France	BAXTER SAS 6 Avenue Louis Pasteur 78310 MAUREPAS FRANCE	TISSUCOL KIT	1st Component: Fibrinogen human 90,00 mg /ml Factor XIII : 10,00 UI/ml Fibronectin : 5,50 mg/ml Plasminogen : 0,08 mg/ml Aprotinin 3000,0 UIK*** /ml 2nd Component: Thrombin 500 UI/ml	Powder, solution and solvent for sealant	Epileisional use
Germany	Baxter Deutschland GmbH Edisonstr. 4 D-85716 Unterschleißheim Germany	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Germany	Baxter Deutschland GmbH Edisonstr. 4 D-85716 Unterschleißheim Germany	Tissucol-Duo S 0,5 ml/1ml/2 ml Immuno	Component 1 Fibrinogen: 70-110 mg/ml Coagulation factor XIII: 10-50 I.E./ml Plasmafibrinectin: 2-9 mg/ml Aprotinin (bovin): 3000 KIE/ml Component 2 Thrombin (human) 500 I.E./ml Calcium chloride: 5,88 mg/ml	Powder and solvent for sealant	Epileisional use
Germany	Baxter Deutschland GmbH Edisonstr. 4 D-85716 Unterschleißheim Germany	Tissucol-Kit 1,0/2,0/5,0 Immuno	Component 1: Fibrinogen: 70 - 110 mg/ml Plasmafibrinectin: 2 - 9 mg/ml Coagulation factor XIII: 10 - 50 I.E./ml Aprotininsolution: 3000 KIE/ml Component 2: Thrombin S lyophilized: 500 I.E./ml Thrombin L lyophilized: 4 I.E./ml Calcium chloride: 5,88 mg/ml	Powder and solvent for sealant	Epileisional use
Greece	BAXTER HELLAS LTD 3 Metsovou str, 14121-N Irakleio, Athens Greece	ARTISS	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use
Greece	BAXTER HELLAS LTD 3 Metsovou str, 14121-N Irakleio, Athens Greece	TISSEEL	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use
Greece	BAXTER HELLAS LTD 3 Metsovou str, 14121-N Irakleio, Athens Greece	TISSEEL LYO	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Epileisional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Hungary	Baxter Hungary Kft. Népfürdő u. 22. IX. em. 1138 Budapest Hungary	TISSEEL LYO por és oldószer szövetragasztóhoz	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Epilesional use
Hungary	Baxter AG Industriestraße 67 1221 Vienna Austria	TISSUCOL Kit 1,0 kétkomponensű fibrinragasztó	1st Component: Total Protein 100-130 mg; Clottable protein: 75-115 mg, thereof Fibrinogen 70-110 mg; Plasma Fibronectin 2-9 mg; Factor XIII 10-50 UI; Plasminogen 0.04-0.12 mg; Aprotinin 3000 KIU; 2nd Component: Thrombin 500 IU or Thrombin 4 UI; Calcium Chlorid Dihydrate 5.88 mg	Powder and solvent for sealant	Epilesional use
Hungary	Baxter AG Industriestraße 67 1221 Vienna Austria	TISSUCOL Kit 2,0 kétkomponensű fibrinragasztó	1st Component: Total Protein 200-260 mg; Clottable protein: 150-230 mg, thereof Fibrinogen 140-220 mg; Plasma Fibronectin 4-18 mg; Factor XIII 20-100 UI; Plasminogen 0.08-0.24 mg; Aprotinin 6000 KIU; 2nd Component: Thrombin 1000 IU or Thrombin 8 UI; Calcium Chlorid Dihydrate 11.76 mg	Powder and solvent for sealant	Epilesional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Hungary	Baxter AG Industriestraße 67 1221 Vienna Austria	TISSUCOL Kit 5,0 kétkomponensű fibrinragasztó	1st Component: Total Protein 500-650 mg; Clottable protein: 375-575 mg, thereof Fibrinogen 350-550 mg; Plasma Fibronectin 10-45 mg; Factor XIII 50-250 UI; Plasminogen 0.2-0.6 mg; Aprotinin 15000 KIU; 2nd Component: Thrombin 2500 IU or Thrombin 20 UI; Calcium Chlorid Dihydrate 29.4 mg	Powder and solvent for sealant	Epilecional use
Iceland	Baxter Medical AB, Isafjordstgatan 30B P.O. Box 63 164 94 Kista, Sweden	Artiss	Human Fibrinogen 91 mg/ml Aprotinum INN 3000 KIU/ml (bovine) Human Thrombin 4 ae^3/ml Calcium Chloride 40 micromol/ml	Solution for sealant	Epilecional use
Iceland	Baxter AG Industriestraße 67 1221 Vienna Austria	TISSEEL	Human Fibrinogen 91 gm/ml Human Factor XIII 10 IU/ml Bovine Aprotinin 3000 IU/ml Human Thrombin 500 IU/ml Calcium Chloride 40 micromol/ml	Solution for sealant	Epilecional use
Iceland	Baxter AG Industriestraße 67 1221 Vienna Austria	Tisseel Duo Quick	Tisseel solution Per ml - Fibrinogen 90 mg Fibronectin 5,5 mg Factor XIII 30 a.e Aprotinin (bovel) 3000 KIU Plasminogen 80 microgram Thrombin solution per ml Human thrombin 500 ae Calcium chloridum 40 micromol	Solution for sealant	Epilecional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Ireland	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	Artiss solutions for sealant, deep frozen	Human Fibrinogen: 72-110 mg/ml Aprotinin: 3000 KIU/ml Human Thrombin: 4 IU/ml Calcium Chloride: 40 µmol/ml	Solution for sealant	Epileisional use
Ireland	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	Tiseel Ready to use Solutions for Sealant	Human Fibrinogen: 72/110 mg/ml Aprotinin: 3000 KIU/ml Human Thrombin: 500 IU/ml Calcium Chloride: 40 µmol/ml	Solution for sealant	Epileisional use
Ireland	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	TISSEEL Lyo	Human Fibrinogen: 72/110 mg/ml Aprotinin: 3000 KIU/ml Human Thrombin: 500 IU/ml Calcium Chloride: 40 µmol/ml	Powder and solvent for sealant	Epileisional use
Italy	Baxter S.p.A. Piazzale dell'Industria, 20 00144 Roma Italy	ARTISS	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium Chloride: 40 µmol/ml	Solution for sealant	Epileisional use
Italy	Baxter AG Industriestraße 67 1221 Vienna Austria	TISSEEL	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU Thrombin: 500 UI/ML Calcium Chloride: 40 MMO LI/L Factor XIII ≤ 10 UI/ml	Solution for sealant	Epileisional use
Luxembourg	Baxter SA Boulevard René Branquart 80 7860 Lessines Belgium	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Luxembourg	Baxter AG Industriestraße 67 1221 Vienna Austria	Tissucol S/D Kit	Fibrinogene humain (protéines coagulables) 72-110 mg/ml Facteur XIII ≤ 10 UI/ml Aprotinine 3000 UIK/ml Thrombine humaine 500 UI/ml Chlorure de calcium 40 µmol/ml	Powder and solvent for sealant	Epileisional use
Malta	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	TISSEEL KIT 2.0 ml, Two- Component Fibrin Sealant	Fibrinogen: 70-110mg/ml Plasmafibrinectin (CIG): 2-9mg/ml Factor XIII: 10-50 U/ml Plasminogen: 0.04 - 0.12mg/ml	Powder and solvent for sealant	Cutaneous Use
Malta	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	TISSEEL Lyo, Two- Component Fibrin Sealant	Fibrinogen: 72-110mg/ml Aprotinin: 3000KIU/ml Thrombin: 500 IU/ml in 45-55mg total protein Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Cutaneous Use
Norway	Baxter AS, Gjerdrumsvei 11, 0484 Oslo, Norway	Artiss	Human Fibrinogen: 91mg ¹ / ml Aprotinin: 3000 KIU ² /ml Human Thrombin: 4IU ³ /ml Calcium Chloride:40µmol/ml	Solution for sealant	Epileisional use
Norway	Baxter AS, Gjerdrumsvei 11, 0484 Oslo, Norway	Tisseel	Human Fibrinogen: 91 mg ¹ /ml Aprotinin: 3000 KIU ² /ml Human Thrombin: 500 IU ³ /ml Calcium Chloride: 40 µmol/ml	Solution for sealant	Epileisional use
Norway	Baxter AS, Gjerdrumsvei 11, 0484 Oslo, Norway	Tisseel	Human Fibrinogen: 91 mg ¹ /ml Aprotinin: 3000 KIU ² /ml Human Thrombin: 500 IU ³ /ml Calcium Chloride: 40 µmol/ml	Powder and solvent for sealant	Epileisional use
Poland	Baxter Polska Sp. z o.o. ul. Kruczkowskiego 8 00-380 Warszawa Poland	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Poland	Baxter Polska Sp. z o.o. ul. Kruczkowskiego 8 00-380 Warszawa Poland	Tisseel	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Poland	Baxter Polska Sp. z o.o. ul. Kruczkowskiego 8 00-380 Warszawa Poland	Tisseel Lyo	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Epilesional use
Portugal	Baxter Médico-Farmacêutica, Lda. Zona Industrial da Abrunheira - Edifício 10 - Sintra Business Park 2710-089 Sintra Portugal	Artiss	Human fibrinogen: 91 mg/ml Aprotinin: 3000 KUI2/ml Human thrombin: 4 UI3/ml Calcium chloride: 40 mmol/ml	Solvent for sealant	Epilesional use
Portugal	Baxter Médico-Farmacêutica, Lda. Zona Industrial da Abrunheira - Edifício 10 - Sintra Business Park 2710-089 Sintra Portugal	Tisseel	Human fibrinogen: 72-110 mg/ml Factor xiii: ≤10 UI Aprotinin: 3000 KUI2/ml Human thrombin: 500 UI3/ml Calcium chloride: 40 micromol/ml	Sealant	Epilesional use
Portugal	Baxter Médico-Farmacêutica, Lda. Zona Industrial da Abrunheira - Edifício 10 - Sintra Business Park 2710-089 Sintra Portugal	Tisseellyo	Human fibrinogen (72-110 mg/ml) Factor xiii (≤10 UI) Aprotinin (3000 KUI2/ml) Human thrombin (500 UI3/ml) Calcium chloride (40micromol/ml)	Powder and solvent for sealant	Epilesional use
Spain	BAXTER, S.L. Polígono Industrial Sector 14 Pouet de Camilo, 2 46394 Ribarroja del Turia Valencia Spain	ARTISS soluciones para adhesivo tisular Ultracongeladas	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Intralesional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Spain	BAXTER, S.L. Polígono Industrial Sector 14 Pouet de Camilo, 2 46394 Ribarroja del Turia Valencia Spain	TISSUCOL DUO 2,0 ml	Syringe TISSUCOL-APROTININ: Total Proteins 100-130 mg/ml; clottable protein 75-115 mg/ml, of which fibrinogen 70-110 mg/ml and plasmatic fibronectin 2-9 mg/ml: Factor XIII 10-50 UI/ml; Plasminogen 0.04-0.12 mg/ml; Aprotinin 3000 UIK/ml (1.67 UPE/ml); Syringe THROMBIN-CALCIUM CHLORIDE: Proteins 50mg/ml; Thrombin 500 UI/ml; calcium chloride 40 µmol/ml	Solution for sealant	Epileisional use
Spain	BAXTER, S.L. Polígono Industrial Sector 14 Pouet de Camilo, 2 46394 Ribarroja del Turia Valencia Spain	TISSUCOL DUO 5,0 ml	Syringe TISSUCOL-APROTININ: Total Proteins 100-130 mg/ml; clottable protein 75-115 mg/ml, of which fibrinogen 70-110 mg/ml and plasmatic fibronectin 2-9 mg/ml: Factor XIII 10-50 UI/ml; Plasminogen 0.04-0.12 mg/ml; Aprotinin 3000 UIK/ml (1.67 UPE/ml); Syringe THROMBIN-CALCIUM CHLORIDE: Proteins 50mg/ml; Thrombin 500 UI/ml; calcium chloride 40 µmol/ml	Solution for sealant	Epileisional use
Sweden	Baxter Medical AB, Isafjordstgatan 30B P.O. Box 63 164 94 Kista, Sweden	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use
Sweden	Baxter AG Industriestraße 67 A- 1221 Vienna Austria	Tisseel	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml Factor XIII: 10 IU/ml	Solution for sealant	Epileisional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Sweden	Baxter AG Industriestraße 67 A- 1221 Vienna Austria	Tisseel Duo Quick	Fibrinogen: 90 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml Factor XIII: 30 IU/ml Plasminogen: 0,08 mg/ml Fibronectin: 5,5 mg/ml	Solution for sealant	Epileisional use
The Netherlands	Baxter B.V. Kobaltweg 49, Utrecht 3542 CE The Netherlands	ARTISS, oplossingen voor weefsellijm (RVG 100631)	Fibrinogen: 91 mg/ml Aprotinin: 3000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epileisional use
The Netherlands	Baxter AG Industriestraße 67 A- 1221 Vienna Austria	Tisseel (RVG 35050/1/2)	Fibrinogen: 91 mg/ml Aprotinin (synthetic): 3000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml Factor XIII: ≤ 10 IU/ml	Solution for sealant	Epileisional use
The Netherlands	Baxter AG Industriestraße 67 A- 1221 Vienna Austria	Tissucol Duo (RVG 17099)	Fibrinogen: 70 - 110 mg/ml Fibronectine 2 - 9 mg/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml Factor XIII: 10-50 IU/ml Aprotinine (bovine): 3000 KIU/ml	Solution for sealant	Epileisional use
The Netherlands	Baxter AG Industriestraße 67 A- 1221 Vienna Austria	Tissucol, Kit (RVG 17100/1/2/3)	Fibrinogen: 70 - 110 mg/ml Fibronectine 2 - 9 mg/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml Factor XIII: 10 - 50 IU/ml Aprotinine (bovine): 3000 KIU/ml	Powder and solvent for sealant	Epileisional use
United Kingdom	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	Artiss, solution for sealant deep frozen	Human fibrinogen: 110mg/ml Aprotinin: 3750KIU/ml Human thrombin: 6.5IU/ml Calcium chloride: 44mcmol/ml	Solution for sealant	Epileisional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	Tisseel Lyo Two- component Fibrin Sealant	Fibrinogen: 75mg Human thrombin: 500 IU Aprotinin: 3000KIU Calcium chloride: 40 mcmol/ml	Powder for sealant and Solution for sealant	Epilesional use
United Kingdom	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	Tisseel Ready to use Solutions for Sealant	Human fibrinogen: 110mg/ml Aprotinin: 3000KU/ml Human thrombin: 500 iu/ml Calcium chloride: 40mcmol/ml	Solution for sealant	Epilesional use

Beriplast and associated names

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Austria	CSL Behring GmbH Emil-von-Behring-Straße 76 D-35041 Marburg Germany	Beriplast P Combi- Set Pulver und Lösungsmittel für einen Gewebekleber	Fibrinogen: 90 mg/ml Coagulation factor XIII: 60 U/ml Aprotinin: 1000 KIU = 0,56 EPU Thrombin: 500 IU /ml Calcium chloride (dihydrate): 5,9 mg/ml	Powder and solvent for sealant	Epilesional use
France	CSL Behring GmbH Emil-von-Behring-Straße 76 D-35041 Marburg Germany	BERIPLAST P 0.5 ml, 1 ml, 3 ml, powders and solvents for sealant Combi-Set	Fibrinogen: 90 mg/ml Coagulation factor XIII: 60 U/ml Aprotinin: 1000 KIU = 0,56 EPU Thrombin: 500 IU /ml Calcium chloride (dihydrate): 5,9 mg/ml	Powder and solvent for sealant	Epilesional use
Germany	CSL Behring GmbH Emil-von-Behring-Straße 76 D-35041 Marburg Germany	Beriplast P Combi- Set 0,5ml/1ml/3ml	Combi-Set 1: Fibrinogen: 90 mg/ml Coagulation factor XIII: 60 U/ml Aprotinin: 1000 KIU/ml=0.56 PEU/ml Combi-Set 2: Thrombin: 500 IU/ml Calcium chloride: 5,9 mg/ml	Powder and solvent for sealant	Epilesional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Greece	CSL BEHRING 5 Hadjiyianni Mexi str, 11528-Athens Greece	BERIPLAST P	Fibrinogen: 90 mg/ml Factor XIII: 60 U/ml Aprotinin: 1000 UIC/ml Thrombin: 500 UI/ml Calcium chloride dihydrate: 5,9 mg/ml	Powder and solvent for sealant	Epileisional use
Greece	CSL BEHRING 5 Hadjiyianni Mexi str, 11528-Athens Greece	BERIPLAST P	Fibrinogen: 90 mg/ml Factor XIII: 60 U/ml Aprotinin: 1000 UIC/ml Thrombin: 500 UI/ml Calcium chloride dihydrate: 5,9 mg/ml	Powder and solvent for sealant	Epileisional use
Greece	CSL BEHRING 5 Hadjiyianni Mexi str, 11528-Athens Greece	BERIPLAST P	Fibrinogen: 90 mg/ml Factor XIII: 60 U/ml Aprotinin: 1000 UIC/ml Thrombin: 500 UI/ml Calcium chloride dihydrate: 5,9 mg/ml	Powder and solvent for sealant	Epileisional use
Hungary	CSL Behring GmbH Emil-von-Behring-Straße 76 D-35041 Marburg Germany	BERIPLAST P COMBI-SET 1 ml szövetragasztó készlet	Combi-Set 1: fibrinogen: 90 mg/ml coagulation factor XIII: 60 U/ml aprotinin: 1000 KIU/ml=0.56 PEU/ml Combi-Set 2: thrombin: 500 IU/ml	Powder and solvent for sealant	Epileisional use
Hungary	CSL Behring GmbH Emil-von-Behring-Straße 76 D-35041 Marburg Germany	BERIPLAST P COMBI-SET 3 ml szövetragasztó készlet	Combi-Set 1: fibrinogen: 90 mg/ml coagulation factor XIII: 60 U/ml aprotinin: 1000 KIU/ml=0.56 PEU/ml Combi-Set 2: thrombin: 500 IU/ml	Powder and solvent for sealant	Epileisional use
Italy	CSL Behring GmbH Emil-von-Behring-Straße 76 D-35041 Marburg Germany	BERIPLAST P	Fibrinogen: 90 mg/ml Factor XIII: 60 U/ml Aprotinin: 1000 KIU/ml Thrombin: 500 IU/ml Calcium Chloride: 5.9 mg/ml	Powder and solvent for sealant	Epileisional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	CSL Behring GmbH, Emil-von-Behring-Strasse 76 35041 Marburg Germany	Beriplast P Combi- Set, weefsellijm - 26655/6/7	Fibrinogen: 90 mg/ml Aprotinin (bovine): 1000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 5,9 mg/ml Factor XIII: 60 U/ml	Powder and solvent for sealant	Epilesional use
Slovak Republic	CSL Behring GmbH, Emil-von-Behring-Strasse 76 35041 Marburg Germany	Beriplast P Combi- Set 0,5 ml, Beriplast P Combi- Set 1 ml, Beriplast P Combi- Set 3 ml	Human fibrinogen: 90 mg Coagulation factor XIII: 60 UI Aprotinin: 1000 KUI Trombin: 7,6 mg Calcium chloride: 5,9 mg	Powder and solvent for tissue sealant	Epilesional use
Slovenia	CSL Behring GmbH, Emil-von-Behring-Strasse 76 35041 Marburg Germany	Beriplast P Combi- Set 1 ml prašek in vehikel za lepilo za tkiva	Human fibrinogen: 90 mg/ml Coagulation factor XIII: 60 e/ml Aprotinin: 1000 EIK/ml Thrombin: 7,6 mg/ml Calcium chloride: 5,9 mg/ml	Powder and solvent for tissue sealant	Epilesional use
Slovenia	CSL Behring GmbH, Emil-von-Behring-Strasse 76 35041 Marburg Germany	Beriplast P Combi- Set 3 ml prašek in vehikel za lepilo za tkiva	Human fibrinogen: 90 mg/ml Coagulation factor XIII: 60 e/ml Aprotinin: 1000 EIK/ml Thrombin: 7,6 mg/ml Calcium chloride: 5,9 mg/ml	Powder and solvent for tissue sealant	Epilesional use
Spain	CSL Behring GmbH, Emil-von-Behring-Strasse 76 35041 Marburg Germany	BERIPLAST P COMBI-SET 0,5 ml	Fibrinogen: 90 mg/ml Coagulation factor XIII: 60 U/ml Aprotinin: 1000 KIU = 0,56 EPU Thrombin: 500 IU /ml Calcium chloride (dihydrate): 5,9 mg/ml	Powder and solvent for sealant	Epilesional use
Spain	CSL Behring GmbH, Emil-von-Behring-Strasse 76 35041 Marburg Germany	BERIPLAST P COMBI-SET 1 ml	Fibrinogen: 90 mg/ml Coagulation factor XIII: 60 U/ml Aprotinin: 1000 KIU = 0,56 EPU Thrombin: 500 IU /ml Calcium chloride (dihydrate): 5,9 mg/ml	Powder and solvent for sealant	Epilesional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Spain	CSL Behring GmbH, Emil-von-Behring-Strasse 76 35041 Marburg Germany	BERIPLAST P COMBI-SET 3 ml	Fibrinogen: 90 mg/ml Coagulation factor XIII: 60 U/ml Aprotinin: 1000 KIU = 0,56 EPU Thrombin: 500 IU /ml Calcium chloride (dihydrate): 5,9 mg/ml	Powder and solvent for sealant	Epilesional use