

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 March 2013 to 31 March 2013

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC ⁽¹⁾ or Article 38 of Directive 2001/82/EC ⁽²⁾)

(2013/C 121/03)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
15.3.2013	Fibrinogen	See Annex I	See Annex I	19.3.2013

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 311, 28.11.2001, p. 1.

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: 3 000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Austria	Baxter AG Industriestraße 67 1221 Vienna Austria	ARTISS LYO – Pulver und Lösungsmittel für einen Gewebekleber	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIE/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Epilesional use
Austria	Baxter AG Industriestraße 67 1221 Vienna Austria	Tisseel - Lösungen für einen Gewebekleber	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Austria	Baxter AG Industriestraße 67 1221 Vienna Austria	Tisseel Lyo - Pulver und Lösungsmittel für einen Gewebekleber	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Epilesional use
Belgium	Baxter SA Boulevard René Branquart 80 7860 Lessines Belgium	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional 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 3 000 UIK/ml (1,67 UPE/ml); Syringe THROMBIN-CALCIUM CHLORIDE: Proteins 50 mg/ml; Thrombin 500 UI/ml; calcium chloride 40 µmol/ml	Solution for sealant	Epilesional 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 3 000 UIK/ml (1,67 UPE/ml); Bottle 3: Human Thrombin 500 IU/ml; Proteins 50 mg/ml; Bottle 4: Human Thrombin 4 UI/ml; Proteins 50 mg/ml; Bottle 5: calcium chloride 40 µmol/ml	Powder and solvent for sealant	Epilesional 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: 3 000 UIK/ml Human Thrombin: 500 UI/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional 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: 3 000 UIK/ml Human Thrombin: 500 UI/ml Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Epilesional use
Bulgaria	Baxter d.o.o. Zelezna cesta 18 1000 Ljubljana Slovenia	Artiss solution for sealant frozen	Human fibrinogen 91 mg/ml Aprotinin 3 000 KIU/ml Human Thrombin 4 IU/ml Calcium Chloride 40 µmol/ml	Solution for sealant	Epilesional 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 3 000 KIU/ml Human Thrombin 4 IU/ml Calcium Chloride 40 µmol/ml	Powder and solvent for sealant	Epilesional use
Bulgaria	Baxter d.o.o. Zelezna cesta 18 1000 Ljubljana Slovenia	Tisseel solutions for sealant	Human fibrinogen 72-110 mg/ml Aprotinin 3 000 KIU/ml Human Thrombin 500 IU/ml Calcium Chloride 40 µmol/ml	Solution for sealant	Epilesional use
Czech Republic	Baxter Czech spol. s r.o. Karla Engliša 3201/6 150 00 Praha 5 Czech Republic	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional 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 Engliše 3201/6 150 00 Praha 5 Czech Republic	Tisseel	Fibrinogen: 91 mg/ml Aprotinin: 3 000 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 Engliše 3201/6 150 00 Praha 5 Czech Republic	Tisseel Lyo	Fibrinogen: 91 mg/ml Aprotinin: 3 000 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: 3 000 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 90 mg/ml Fibronectin 6 mg/ml Aprotinin 3 000 KIE/ml Coagulation Factor XIII 30 IE/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: 3 000 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: 3 000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Topical
Finland	Baxter AG Industriestraße 67 1221 Vienna Austria	Tisseel	Fibrinogen 72-110 mg/ml Factor XIII coagulationis humanus 10 IU/ml Aprotinin: 3 000 KIU/ml Thrombin: 500 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 duo quick	Plasmaproteinum humanum 100-130 mg/ml: Fibrinogen 90 mg/ml Plasmafibrinonectinum 5,5 mg/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 50 mg/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: 3 000 KIE/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional 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 3 000,0 UIK***/ml 2nd Component: Thrombin 500 UI/ml	Powder, solution and solvent for sealant	Epilesional use
Germany	Baxter Deutschland GmbH Edisonstr. 4 D-85716 Unterschleißheim Germany	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Germany	Baxter Deutschland GmbH Edisonstr. 4 D-85716 Unterschleißheim Germany	Tissucol-Duo S 0,5 ml/1 ml/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): 3 000 KIE/ml Component 2 Thrombin (human) 500 I.E./ml Calcium chloride: 5,88 mg/ml	Powder and solvent for sealant	Epilesional 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: 3 000 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	Epilesional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Greece	BAXTER HELLAS LTD 3 Metsovou str, 14121-N Irakleio, Athens Greece	ARTISS	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Greece	BAXTER HELLAS LTD 3 Metsovou str, 14121-N Irakleio, Athens Greece	TISSEEL	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Greece	BAXTER HELLAS LTD 3 Metsovou str, 14121-N Irakleio, Athens Greece	TISSEEL LYO	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Epilesional use
Hungary	Baxter Hungary Kft. Népfürdő u. 22. IX. em. 1138 Budapest Hungary	TISSEEL LYO por és oldószer szövetragasztóhoz	Fibrinogen: 91 mg/ml Aprotinin: 3 000 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 3 000 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 6 000 KIU; 2nd Component: Thrombin 1 000 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 15 000 KIU; 2nd Component: Thrombin 2 500 IU or Thrombin 20 UI; Calcium Chlorid Dihydrate 29,4 mg	Powder and solvent for sealant	Epilesional use
Iceland	Baxter Medical AB, Isafjordstgatan 30B P.O. Box 63 164 94 Kista, Sweden	Artiss	Human Fibrinogen 91 mg/ml Aprotinum INN 3 000 KIU/ml (bovine) Human Thrombin 4 ae ³ /ml Calcium Chloride 40 micromol/ml	Solution for sealant	Epilesional use
Iceland	Baxter AG Industriestraße 67 1221 Vienna Austria	TISSEEL	Human Fibrinogen 91 gm/ml Human Factor XIII 10 IU/ml Bovine Aprotinin 3 000 IU/ml Human Thrombin 500 IU/ml Calcium Chloride 40 micromol/ml	Solution for sealant	Epilesional 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) 3 000 KIU Plasminogen 80 microgram Thrombin solution per ml Human thrombin 500 ae Calcium chloridum 40 micromol	Solution for sealant	Epilesional use
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: 3 000 KIU/ml Human Thrombin: 4 IU/ml Calcium Chloride: 40 µmol/ml	Solution for sealant	Epilesional 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: 3 000 KIU/ml Human Thrombin: 500 IU/ml Calcium Chloride: 40 µmol/ml	Solution for sealant	Epilesional 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	TISSEEL Lyo	Human Fibrinogen: 72/110 mg/ml Aprotinin: 3 000 KIU/ml Human Thrombin: 500 IU/ml Calcium Chloride: 40 µmol/ml	Powder and solvent for sealant	Epilesional use
Italy	Baxter S.p.A. Piazzale dell'Industria, 20 00144 Roma Italy	ARTISS	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 4 IU/ml Calcium Chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Italy	Baxter AG Industriestraße 67 1221 Vienna Austria	TISSEEL	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU Thrombin: 500 UI/ML Calcium Chloride: 40 MMO LI/L Factor XIII ≤ 10 UI/ml	Solution for sealant	Epilesional use
Luxembourg	Baxter SA Boulevard René Branquart 80 7860 Lessines Belgium	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Luxembourg	Baxter AG Industriestraße 67 1221 Vienna Austria	Tissucol S/D Kit	Fibrinogene humain (proteines coagulables) 72-110 mg/ml Facteur XIII ≤ 10 UI/ml Aprotinine 3 000 UIK/ml Thrombine humaine 500 UI/ml Chlorure de calcium 40 µmol/ml	Powder and solvent for sealant	Epilesional use
Malta	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	TISSEEL KIT 2,0 ml, Two- Component Fibrin Sealant	Fibrinogen: 70-110 mg/ml Plasmafibronectin (CIG): 2-9 mg/ml Factor XIII: 10-50 U/ml Plasminogen: 0,04 - 0,12 mg/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: 72-110 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 500 IU/ml in 45-55 mg total protein Calcium chloride: 40 µmol/ml	Powder and solvent for sealant	Cutaneous Use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
Norway	Baxter AS, Gjerdrumsvei 11, 0484 Oslo, Norway	Artiss	Human Fibrinogen: 91 mg ¹ /ml Aprotinin: 3 000 KIU ² /ml Human Thrombin: 4 IU ³ /ml Calcium Chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Norway	Baxter AS, Gjerdrumsvei 11, 0484 Oslo, Norway	Tisseel	Human Fibrinogen: 91 mg ¹ /ml Aprotinin: 3 000 KIU ² /ml Human Thrombin: 500 IU ³ /ml Calcium Chloride: 40 µmol/ml	Solution for sealant	Epilesional use
Norway	Baxter AS, Gjerdrumsvei 11, 0484 Oslo, Norway	Tisseel	Human Fibrinogen: 91 mg ¹ /ml Aprotinin: 3 000 KIU ² /ml Human Thrombin: 500 IU ³ /ml Calcium Chloride: 40 µmol/ml	Powder and solvent for sealant	Epilesional use
Poland	Baxter Polska Sp. z o.o. ul. Kruczkowskiego 8 00-380 Warszawa Poland	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 4 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	Fibrinogen: 91 mg/ml Aprotinin: 3 000 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: 3 000 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: 3 000 KIU ² /ml Human thrombin: 4 UI ³ /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: 3 000 KU ¹ ² /ml Human thrombin: 500 UI ³ /ml Calcium chloride: 40 micromol/ml	Sealant	Epilesional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
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 (3 000 KIU ² /ml) Human thrombin (500 UI ³ /ml) Calcium chloride (40 micromol/ml)	Powder and solvent for sealant	Epilesional use
Spain	BAXTER, S.L. Polígono Industrial Sector 14 Pouet de Camilo, 246394 Ribarroja del Turia Valencia Spain	ARTISS soluciones para adhesivo tisular Ultracongeladas	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 μ mol/ml	Solution for sealant	Intralesional use
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 3 000 UIK/ml (1,67 UPE/ml); Syringe THROMBIN-CALCIUM CHLORIDE: Proteins 50 mg/ml; Thrombin 500 UI/ml; calcium chloride 40 μ mol/ml	Solution for sealant	Epilesional 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 3 000 UIK/ml (1,67 UPE/ml); Syringe THROMBIN-CALCIUM CHLORIDE: Proteins 50 mg/ml; Thrombin 500 UI/ml; calcium chloride 40 μ mol/ml	Solution for sealant	Epilesional use
Sweden	Baxter Medical AB, Isafjordstgatan 30B P.O. Box 63 164 94 Kista, Sweden	Artiss	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 μ mol/ml	Solution for sealant	Epilesional use
Sweden	Baxter AG Industriestraße 67 A- 1221 Vienna Austria	Tisseel	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 μ mol/ml Factor XIII: 10 IU/ml	Solution for sealant	Epilesional 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: 3 000 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	Epilesional use
The Netherlands	Baxter B.V. Kobaltweg 49, Utrecht 3542 CE The Netherlands	ARTISS, oplossingen voor weefselijm (RVG 100631)	Fibrinogen: 91 mg/ml Aprotinin: 3 000 KIU/ml Thrombin: 4 IU/ml Calcium chloride: 40 µmol/ml	Solution for sealant	Epilesional use
The Netherlands	Baxter AG Industriestraße 67 A- 1221 Vienna Austria	Tisseel (RVG 35050/1/2)	Fibrinogen: 91 mg/ml Aprotinin (synthetic): 3 000 KIU/ml Thrombin: 500 IU/ml Calcium chloride: 40 µmol/ml Factor XIII: ≤ 10 IU/ml	Solution for sealant	Epilesional 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): 3 000 KIU/ml	Solution for sealant	Epilesional 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): 3 000 KIU/ml	Powder and solvent for sealant	Epilesional use
United Kingdom	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	Artiss, solution for sealant deep frozen	Human fibrinogen: 110 mg/ml Aprotinin: 3 750 KIU/ml Human thrombin: 6,5 IU/ml Calcium chloride: 44 mcmol/ml	Solution for sealant	Epilesional use
United Kingdom	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	Tisseel Lyo Two-component Fibrin Sealant	Fibrinogen: 75 mg Human thrombin: 500 IU Aprotinin: 3 000 KIU Calcium chloride: 40 mcmol/ml	Powder for sealant and Solution for sealant	Epilesional 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 Ready to use Solutions for Sealant	Human fibrinogen: 110 mg/ml Aprotinin: 3 000 KU/ml Human thrombin: 500 iu/ml Calcium chloride: 40 mmol/ml	Solution for sealant	Epilepsional 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 Gewebe Kleber	Fibrinogen: 90 mg/ml Coagulation factor XIII: 60 U/ml Aprotinin: 1 000 KIU = 0,56 EPU Thrombin: 500 IU/ml Calcium chloride (dihydrate): 5,9 mg/ml	Powder and solvent for sealant	Epilepsional 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: 1 000 KIU = 0,56 EPU Thrombin: 500 IU/ml Calcium chloride (dihydrate): 5,9 mg/ml	Powder and solvent for sealant	Epilepsional use
Germany	CSL Behring GmbH Emil-von-Behring-Straße 76 D-35041 Marburg Germany	Beriplast P Combi-Set 0,5 ml/1 ml/3 ml	Combi-Set 1: Fibrinogen: 90 mg/ml Coagulation factor XIII: 60 U/ml Aprotinin: 1 000 KIU/ml = 0,56 EPU/ml Combi-Set 2: Thrombin: 500 IU/ml Calcium chloride: 5,9 mg/ml	Powder and solvent for sealant	Epilepsional use
Greece	CSL BEHRING 5 Hadjiyianni Mexi str, 11528-Athens Greece	BERIPLAST P	Fibrinogen: 90 mg/ml Factor XIII: 60 U/ml Aprotinin: 1 000 UIC/ml Thrombin: 500 UI/ml Calcium chloride dihydrate: 5,9 mg/ml	Powder and solvent for sealant	Epilepsional use
Greece	CSL BEHRING 5 Hadjiyianni Mexi str, 11528-Athens Greece	BERIPLAST P	Fibrinogen: 90 mg/ml Factor XIII: 60 U/ml Aprotinin: 1 000 UIC/ml Thrombin: 500 UI/ml Calcium chloride dihydrate: 5,9 mg/ml	Powder and solvent for sealant	Epilepsional 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: 1 000 UIC/ml Thrombin: 500 UI/ml Calcium chloride dihydrate: 5,9 mg/ml	Powder and solvent for sealant	Epilesional 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: 1 000 KIU/ml = 0,56 PEU/ml Combi-Set 2: thrombin: 500 IU/ml	Powder and solvent for sealant	Epilesional 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: 1 000 KIU/ml = 0,56 PEU/ml Combi-Set 2: thrombin: 500 IU/ml	Powder and solvent for sealant	Epilesional 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: 1 000 KIU/ml Thrombin: 500 IU/ml Calcium Chloride: 5,9 mg/ml	Powder and solvent for sealant	Epilesional use
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): 1 000 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: 1 000 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: 1 000 EIK/ml Thrombin: 7,6 mg/ml Calcium chloride: 5,9 mg/ml	Powder and solvent for tissue sealant	Epilesional use

Member State (in EEA)	Marketing Authorisation Holder	Invented name Name	Strength	Pharmaceutical Form	Route of administration
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: 1 000 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: 1 000 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: 1 000 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 3 ml	Fibrinogen: 90 mg/ml Coagulation factor XIII: 60 U/ml Aprotinin: 1 000 KIU = 0,56 EPU Thrombin: 500 IU/ml Calcium chloride (dihydrate): 5,9 mg/ml	Powder and solvent for sealant	Epilesional use