



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 September 2017
EMA/530525/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: aprotinin / calcium chloride / human factor xiii / human fibrinogen / human thrombin, aprotinin / fibrinogen / fibronectin / human coagulation factor XIII / plasma protein fraction / plasminogen / thrombin, aprotinin / human fibrinogen / thrombin / calcium chloride, aprotinin / calcium chloride / factor xiii / human thrombin / human clottable protein containing mainly fibrinogen and fibronectin, calcium chloride / human fibrinogen / factor xiii / fibronectin / plasminogen / human thrombin / bovine aprotinin, calcium chloride / human fibrinogen / factor xiii / fibronectin / human thrombin / bovine aprotinin, human fibrinogen / calcium chloride dihydrate / plasma fibronectin / thrombin / bovine aprotinin / human coagulation factor xiii, human fibrinogen / calcium chloride dihydrate / plasma protein fraction / fibronectin / thrombin / bovine aprotinin / human coagulation factor xiii, human fibrinogen / plasminogen / human thrombin / bovine aprotinin / human coagulation factor xiii / human

Procedure no.: PSUSA/00010346/201611



Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
SILKETAL Polvere e solvente per adesivo tissutale	not available	042046019	KEDRION S.P.A.	IT
SILKETAL Polvere e solvente per adesivo tissutale	not available	042046021	KEDRION S.P.A.	IT
SILKETAL Polvere e solvente per adesivo tissutale	not available	042046033	KEDRION S.P.A.	IT
KolFib Polvere e solvente per adesivo tissutale	not available	044152015	KEDRION S.P.A.	IT
KolFib Polvere e solvente per adesivo tissutale	not available	044152027	KEDRION S.P.A.	IT
KolFib Polvere e solvente per adesivo tissutale	not available	044152039	KEDRION S.P.A.	IT
Beriplast P Combi-Set 0,5 ml Prášok a rozpúšťadlo na tkanivové lepidlo	not available	87/0140/85-C/S	CSL BEHRING GMBH	SK
Beriplast P Combi-Set 1 ml Prášok a rozpúšťadlo na tkanivové lepidlo	not available	87/0140/85-C/S	CSL BEHRING GMBH	SK
Beriplast P Combi-Set 3 ml Prášok a rozpúšťadlo na tkanivové lepidlo	not available	87/0140/85-C/S	CSL BEHRING GMBH	SK
Beriplast® P Combi-Set 0,5 ml Pulver und Lösungsmittel für einen Gewebekleber	DE/H/0135/001	PEI.H.00322.01.1	CSL BEHRING GMBH	DE
Beriplast® P Combi-Set 1 ml Pulver und	DE/H/0135/002	PEI.H.00322.02.1	CSL BEHRING GMBH	DE

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Lösungsmittel für einen Gewebekleber				
Beriplast® P Combi-Set 3 ml Pulver und Lösungsmittel für einen Gewebekleber	DE/H/0135/003	PEI.H.00322.03.1	CSL BEHRING GMBH	DE
BERIPLAST, poudres et solvants pour colle Combi-set	DE/H/0135/001	NL 23403	CSL BEHRING GMBH	FR
BERIPLAST, poudres et solvants pour colle Combi-set	DE/H/0135/002	NL 23403	CSL BEHRING GMBH	FR
BERIPLAST, poudres et solvants pour colle Combi-set	DE/H/0135/003	NL 23403	CSL BEHRING GMBH	FR
Beriplast PCombi-Set 0,5 ml Συγκολλητικό ιστών, κόνεις και διαλύτες για παρασκευή	DE/H/0135/001	12108/25-02-2011	CSL BEHRING MEPE	GR
Beriplast P Combi-Set 1 ml Συγκολλητικό ιστών, κόνεις και διαλύτες για παρασκευή	DE/H/0135/002	12122/25-02-2011	CSL BEHRING MEPE	GR
Beriplast P Combi-Set 3 ml Συγκολλητικό ιστών, κόνεις και διαλύτες για παρασκευή	DE/H/0135/003	12123/25-02-2011	CSL BEHRING MEPE	GR
ARTISS Lösungen für	AT/H/0186/001	BE340961	BAXTER SA	BE

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Gewebekleber Tiefgekühlt				
ARTISS Lösungen für Gewebekleber Tiefgekühlt	AT/H/0186/001	BE340977	BAXTER SA	BE
ARTISS Lösungen für Gewebekleber Tiefgekühlt	AT/H/0186/001	BE340986	BAXTER SA	BE
TISSEEL Lyo prašci i otapala za tkivno ljepilo	not available	UP/I-530-09/13-02/219	AGMAR D.O.O.	HR
TISSEEL S/D 2 ml Lösungen für Gewebekleber	not available	BE403602	BAXTER SA	BE
TISSEEL S/D 4 ml Lösungen für Gewebekleber	not available	BE403611	BAXTER SA	BE
TISSEEL S/D 10 ml Lösungen für Gewebekleber	not available	BE403627	BAXTER SA	BE
TISSEEL 2 ml	AT/H/0317/001	PEI.H.11728.01.1	BAXTER DEUTSCHLAND GMBH	DE
TISSEEL 4 ml	AT/H/0317/001	PEI.H.11728.02.1	BAXTER DEUTSCHLAND GMBH	DE
TISSEEL 10 ml	AT/H/0317/001	PEI.H.11728.03.1	BAXTER DEUTSCHLAND GMBH	DE
TISSEEL – Solutions for sealant	not available	MA 161/02503	BAXTER HEALTHCARE LTD.	MT
Tisseel roztoky na tkanivové lepidlo	AT/H/0317/001	87/0388/14-S	BAXTER SLOVAKIA S.R.O.	SK
TISSEEL, solutions pour	AT/H/0317/001	34009 550 008 6 0	BAXTER SAS	FR

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colle				
TISSEEL, solutions pour colle	AT/H/0317/001	34009 550 008 7 7	BAXTER SAS	FR
TISSEEL, solutions pour colle	AT/H/0317/001	34009 550 008 8 4	BAXTER SAS	FR
TISSEEL, solutions pour colle	AT/H/0317/001	34009 550 008 9 1	BAXTER SAS	FR
TISSEEL, solutions pour colle	AT/H/0317/001	34009 550 009 1 4	BAXTER SAS	FR
TISSEEL, solutions pour colle	AT/H/0317/001	34009 550 009 2 1	BAXTER SAS	FR
TISSEEL Soluciones para adhesivo tisular	AT/H/0317/001	78896	BAXTER, S.L.	ES
Artiss, lösningar till vävnadslim	AT/H/0186/001	25732	BAXTER MEDICAL AB	SE
ARTISS, oplossingen voor weefsellijm. Diepgevroren	AT/H/0186/001	RVG 100631	BAXTER B.V.	NL
Artiss, vævsklæber	AT/H/0186/001	41769	BAXTER A/S	DK
Artiss liuokset kudoksiimaa varten, pakastettu	AT/H/0186/001	23792	BAXTER OY	FI
ARTISS Solutions for Sealant Deep frozen	AT/H/0186/001	PA 167/131/001	BAXTER HEALTHCARE LTD.	IE
ARTISS Solutions for Sealant Deep frozen	AT/H0186/001	PL 00116/0634	BAXTER HEALTHCARE LTD.	UK
ARTISS Tiefgefrorene	AT/H/0186/001	PEI.H.03593.01.1	BAXTER DEUTSCHLAND	DE

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Lösungen zur Fibrinklebung			GMBH	
ARTISS Soluciones para adhesivo tisular Ultracongeladas	AT/H/0186/001	70914	BAXTER, S.L.	ES
ARTISS Lausnir fyrir vefjalím, djúpfrystar	AT/H/0186/001	IS/1/07/061/01	BAXTER MEDICAL AB	IS
Tisseel	not available	41378	BAXTER A/S	DK
TISSEEL liuokset kudosliimaa varten	not available	27626	BAXTER OY	FI
TISSEEL Lyo por és oldószer szövetragasztóhoz	AT/H/0317/002	OGYI-T-21589/04	BAXTER HUNGARY KFT.	HU
TISSEEL Lyo por és oldószer szövetragasztóhoz	AT/H/0317/002	OGYI-T-21589/05	BAXTER HUNGARY KFT.	HU
TISSEEL Lyo por és oldószer szövetragasztóhoz	AT/H/0317/002	OGYI-T-21589/06	BAXTER HUNGARY KFT.	HU
ARTISS Διαλύματα για συγκόλληση ιστών Βαθιά κατεψυγμένα	AT/H/0186/001	23891	BAXTER HELLAS	GR
ARTISS Væsker til vevslim, dypfryste	AT/H/0186/001	07-5091	BAXTER AS	NO
TISSEEL – Διάλυμα για συγκόλληση ιστών	AT/H/0317/001	61675	BAXTER HELLAS	GR
Tisseel Lyo - Pulver und	AT/H/0317/002	2-00209	BAXTER MEDICAL PRODUCTS	AT

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Lösungsmittel für einen Gewebekleber			GMBH	
Tisseel - Lösungen für einen Gewebekleber	AT/H/0317/001	2-00071	BAXTER MEDICAL PRODUCTS GMBH	AT
ТИСИЛ ЛИО прахове и разтворители за тъканно лепило TISSEEL LYO powders and solvents for sealant	AT/H/0317/002	20090532	BAXTER BULGARIA EOOD	BG
TISSEEL Roztoky pro tkánové lepidlo	AT/H/0317/001	87/791/09-C	BAXTER CZECH SPOL. S R.O.	CZ
TISSEEL Lyo Prášky a rozpouštědla pro tkánové lepidlo	AT/H/0317/002	87/792/09-C	BAXTER CZECH SPOL. S R.O.	CZ
TISSUCOL KIT, poudres, solution et solvant pour colle intralésionnelle	not available	34009 562 089 4 4	BAXTER SAS	FR
TISSUCOL KIT, poudres, solution et solvant pour colle intralésionnelle	not available	34009 562 090 2 6	BAXTER SAS	FR
TISSUCOL KIT, poudres, solution et solvant pour colle intralésionnelle	not available	34009 562 091 9 4	BAXTER SAS	FR
TISSUCOL KIT, poudres, solution et solvant pour colle intralésionnelle	not available	34009 562 092 5 5	BAXTER SAS	FR
TISSEEL lausnir fyrir vefjalím	not available	IS/1/07/126/01	BAXTER MEDICAL AB	IS

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
TISSEEL Ready to use Solutions for Sealant	not available	PA 167/129/005	BAXTER HEALTHCARE LTD.	IE
TISSEEL LYO powder and solvent for sealant	not available	PA 167/129/6	BAXTER HEALTHCARE LTD.	IE
TISSEEL 2 ml adesivo tissutale	not available	025243179	BAXTER S.P.A.	IT
TISSEEL 4 ml adesivo tissutale	not available	025243181	BAXTER S.P.A.	IT
TISSEEL 10 ml adesivo tissutale	not available	025243193	BAXTER S.P.A.	IT
TISSEEL Ready to use Solutions for Sealant	not available	PL 00116/0627	BAXTER HEALTHCARE LTD.	UK
TISSEEL Lyo Two-Component Fibrin Sealant	not available	PL 00116/0321	BAXTER HEALTHCARE LTD.	UK
Tisseel lösningar till vävnadslim	not available	25151	BAXTER MEDICAL AB	SE
TISSEEL 2 ml Oplossingen voor weefselijm	not available	RVG 35050	BAXTER B.V.	NL
TISSEEL 4 ml Oplossingen voor weefselijm	not available	RVG 35051	BAXTER B.V.	NL
TISSEEL 10 ml Oplossingen voor weefselijm	not available	RVG 35052	BAXTER B.V.	NL
TISSEEL Lyo – proszki i rozpuszczalniki do sporządzania kleju do	AT/H/0317/002	16256	BAXTER POLSKA SP Z O.O.	PL

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tkanek				
Tisseel associação, cola para tecidos	not available	5043476	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Tisseel associação, cola para tecidos	not available	5043500	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Tisseel associação, cola para tecidos	not available	5043518	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Tisseellyo, associação, pó e solvente para cola para tecidos	not available	5043542	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Tisseel associação, cola para tecidos	not available	5396205	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Tisseel associação, cola para tecidos	not available	5396213	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Tisseel associação, cola para tecidos	not available	5396221	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
TISSEEL S/D 2 ml Solutions pour colle	not available	BE403602	BAXTER SA	BE
TISSEEL S/D 4 ml Solutions pour colle	not available	BE403611	BAXTER SA	BE
TISSEEL S/D 10 ml Solutions pour colle	not available	BE403627	BAXTER SA	BE
TISSEEL S/D 2 ml Oplossingen voor weefsellijm	not available	BE403602	BAXTER SA	BE
TISSEEL S/D 4 ml Oplossingen voor	not available	BE403611	BAXTER SA	BE

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weefsellijm				
TISSEEL S/D 10 ml Oplossingen voor weefsellijm	not available	BE403627	BAXTER SA	BE
Tisseel – oppløsning til vevslim	AT/H/0317/001	09-6772	BAXTER AS	NO
Tisseel – pulver og væske til vevslim	AT/H/0317/002	09-6773	BAXTER AS	NO
ARTISS – Lösungen für einen Gewebekleber tiefgefroren	AT/H/0186/001	2-00349	BAXTER MEDICAL PRODUCTS GMBH	AT
ARTISS, Roztoky pro tkánové lepidlo, zmrazené	AT/H/0186/001	87/380/09-C	BAXTER CZECH SPOL. S R.O.	CZ
ARTISS, solutions pour colle Congelées	AT/H/0186/001	34009 575 576 6 9	BAXTER SAS	FR
ARTISS, solutions pour colle Congelées	AT/H/0186/001	34009 575 577 2 0	BAXTER SAS	FR
ARTISS, solutions pour colle Congelées	AT/H/0186/001	34009 575 578 9 8	BAXTER SAS	FR
ARTISS, solutions pour colle Congelées	AT/H/0186/001	BE340961	BAXTER SA	BE
ARTISS, oplossingen voor weefsellijm. Diepgevroren	AT/H/0186/001	BE340961	BAXTER SA	BE

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ARTISS, solutions pour colle Congelées	AT/H/0186/001	BE340977	BAXTER SA	BE
ARTISS, oplossingen voor weefsellijm. Diepgevroren	AT/H/0186/001	BE340977	BAXTER SA	BE
ARTISS, solutions pour colle Congelées	AT/H/0186/001	BE340986	BAXTER SA	BE
ARTISS, oplossingen voor weefsellijm. Diepgevroren	AT/H/0186/001	BE340986	BAXTER SA	BE
ARTISS Soluzione per adesivo tissutale Congelata	AT/H/0186/001	039546015	BAXTER S.P.A.	IT
ARTISS Soluzione per adesivo tissutale Congelata	AT/H/0186/001	039546027	BAXTER S.P.A.	IT
ARTISS, solutions pour colle Congelées	AT/H/0186/001	572539	BAXTER SA	LU
ARTISS, solutions pour colle Congelées	AT/H/0186/001	572542	BAXTER SA	LU
ARTISS, solutions pour colle Congelées	AT/H/0186/001	572556	BAXTER SA	LU
ARTISS Soluzione per adesivo tissutale Congelata	AT/H/0186/001	039546039	BAXTER S.P.A.	IT
ARTISS roztwory do sporzadzania kleju do tkanek Gleboko mrozone	AT/H/0186/001	16281	BAXTER POLSKA SP Z O.O.	PL

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ARTISS Soluções para cola para tecidos Congeladas	AT/H/0186/001	5329479	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
ARTISS Soluções para cola para tecidos Congeladas	AT/H/0186/001	5329503	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
ARTISS Soluções para cola para tecidos Congeladas	AT/H/0186/001	5329511	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Tisseellyo, associação, pó e solvente para cola para tecidos	not available	5043526	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Tisseellyo, associação, pó e solvente para cola para tecidos	not available	5043534	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
TISSEEL – Roztwory do sporządzania kleju do tkanek	AT/H/0317/001	16255	BAXTER POLSKA SP Z O.O.	PL
TISSEEL S/D 2 ml Solutions pour colle	not available	0702602	BAXTER SA	LU
TISSEEL S/D 2 ml Solutions pour colle	not available	0702616	BAXTER SA	LU
TISSEEL S/D 4 ml Solutions pour colle	not available	0702633	BAXTER SA	LU
TISSEEL S/D 4 ml Solutions pour colle	not available	0702647	BAXTER SA	LU
TISSEEL S/D 10 ml Solutions pour colle	not available	0702651	BAXTER SA	LU

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
TISSEEL S/D 10 ml Solutions pour colle	not available	0702664	BAXTER SA	LU