



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 July 2022
EMA/38012/2023
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 fibronectin.

Procedure no.: PSUSA/00010346/202111

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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 Lyo Powder and Solvent for Sealant.	not available	PA2299/025/002	BAXTER HOLDING B.V.	IE
TISSEEL 2 ml Oplossingen voor weefsellijm	not available	RVG 35050	BAXTER B.V.	NL
TISSEEL 4 ml Oplossingen voor weefsellijm	not available	RVG 35051	BAXTER B.V.	NL
TISSEEL 10 ml Oplossingen voor weefsellijm	not available	RVG 35052	BAXTER B.V.	NL
Tisseel lösningar till vävnadslim	not available	25151	BAXTER MEDICAL AB	SE
KoFib Polvere e solvente per adesivo tissutale.	not available	044152015	KEDRION S.P.A.	IT
KoFib Polvere e solvente per adesivo tissutale.	not available	044152027	KEDRION S.P.A.	IT
KoFib Polvere e solvente per adesivo tissutale.	not available	044152039	KEDRION S.P.A.	IT
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
TISSEEL Ready to use Solutions for Sealant	not available	PA2299/025/001	BAXTER HOLDING B.V.	IE
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 roztoky na tkanivové lepidlo	AT/H/0317/001	87/0388/14-S	BAXTER SLOVAKIA S.R.O.	SK
TISSEEL, solutions pour colle	AT/H/0317/001	34009 550 008 6 0	BAXTER SAS	FR
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 Soluciones para adhesivo tisular	AT/H/0317/001	78896	BAXTER, S.L.	ES

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
TISSEEL – Διάλυμα για συγκόλληση ιστών	AT/H/0317/001	61675/17-09-2015	BAXTER HELLAS	GR
Tisseel Lyo - Pulver und Lösungsmittel für einen Gewebekleber	AT/H/0317/002	2-00209	BAXTER MEDICAL PRODUCTS GMBH	AT
Tisseel - Lösungen für einen Gewebekleber	AT/H/0317/001	2-00071	BAXTER MEDICAL PRODUCTS GMBH	AT
ТИСИЛ ЛИО прахове и разтворители за тъканно лепило	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

TISSEEL Lyo – proszki i rozpuszczalniki do sporządzania kleju do tkanek	AT/H/0317/002	16256	BAXTER POLSKA SP Z O.O.	PL
Tisseel – oppløsning til vevslim	AT/H/0317/001	09-6772	BAXTER MEDICAL AB	NO
Tisseel – pulver og væske til vevslim	AT/H/0317/002	09-6773	BAXTER MEDICAL AB	NO
TISSEEL, solutions pour colle	AT/H/0317/001	34009 550 319 0 1	BAXTER SAS	FR
TISSEEL, solutions pour colle	AT/H/0317/001	34009 550 319 1 8	BAXTER SAS	FR
TISSEEL, solutions pour colle	AT/H/0317/001	34009 550 319 2 5	BAXTER SAS	FR
TISSEEL – Roztwory do sporządzania kleju do tkanek	AT/H/0317/001	16255	BAXTER POLSKA SP Z O.O.	PL
TISSEEL – Solutions for sealant	not available	MA 1277/01403	BAXTER HOLDING B.V.	MT
TISSEEL – Solutions for sealant	not available	MA 1277/01402	BAXTER HOLDING B.V.	MT
TISSEEL – Solutions for sealant	not available	MA 1277/01401	BAXTER HOLDING B.V.	MT

ARTISS Lösungen für Gewebekleber Tiefgekühlt	AT/H/0186/001	BE340961	BAXTER SA	BE
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
Artiss, lösningar till vävnadslim	AT/H/0186/001	25732	BAXTER MEDICAL AB	SE
ARTISS, oplossingen voor weefselijm	AT/H/0186/001	RVG 100631	BAXTER B.V.	NL
Artiss, vævsklæber	AT/H/0186/001	41769	BAXTER A/S	DK
ARTISS Liuokset kudoksiin varten, pakastettu	AT/H/0186/001	23792	BAXTER OY	FI
ARTISS Solutions for Sealant Deep frozen	AT/H0186/001	PL00116/0634	BAXTER HEALTHCARE LTD.	XI
ARTISS Tiefgefrorene Lösungen zur Fibrinklebung	AT/H/0186/001	PEI.H.03593.01.1	BAXTER DEUTSCHLAND GMBH	DE
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
ARTISS Διαλύματα για συγκόλληση ιστών Βαθιά κατεψυγμένα	AT/H/0186/001	23891/03-04-2015	BAXTER HELLAS	GR
Artiss Væsker til vevslím, dypfryste	AT/H/0186/001	07-5091	BAXTER MEDICAL AB	NO
ARTISS – Lösungen für einen Gewebekleber tiefgefroren	AT/H/0186/001	2-00349	BAXTER MEDICAL PRODUCTS GMBH	AT
Artiss roztoky pro tkánové lepidlo, hluboce 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 weefselijm. Diepgevroren	AT/H/0186/001	BE340961	BAXTER SA	BE
ARTISS, solutions pour colle Congelées	AT/H/0186/001	BE340977	BAXTER SA	BE
ARTISS, oplossingen voor weefselijm. 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 weefselijm. 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 sporządzania kleju do tkanek Głęboko mrożone	AT/H/0186/001	16281	BAXTER POLSKA SP Z O.O.	PL
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
ARTISS Solutions for Sealant Deep frozen	AT/H/0186/001	PA2299/026/001	BAXTER HOLDING B.V.	IE
ARTISS, solutions pour colle Congelées	AT/H/0186/001	34009 550 817 5 3	BAXTER SAS	FR
ARTISS, solutions pour colle Congelées	AT/H/0186/001	34009 550 817 6 0	BAXTER SAS	FR
ARTISS, solutions pour colle Congelées	AT/H/0186/001	34009 550 817 7 7	BAXTER SAS	FR

Artiss, lösningar till vävnadslim	AT/H/0186/001	23792	BAXTER OY	FI
ARTISS Soluzione per adesivo tissutale Congelata	AT/H/0186/001	039546078	BAXTER S.P.A.	IT
ARTISS Soluzione per adesivo tissutale Congelata	AT/H/0186/001	039546080	BAXTER S.P.A.	IT
ARTISS Soluzione per adesivo tissutale Congelata	AT/H/0186/001	039546092	BAXTER S.P.A.	IT
TISSEEL liuokset kudosliimaa varten	not available	27626	BAXTER OY	FI
Tisseel, lösningar till vävnadslim	not available	27626	BAXTER OY	FI
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
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 Lösungsmittel für einen Gewebekleber	DE/H/0135/002	PEI.H.00322.02.1	CSL BEHRING GMBH	DE
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
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
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 lausnir fyrir vefjalím	not available	IS/1/07/126/01	BAXTER MEDICAL AB	IS
TISSEEL S/D 2 ml Solutions pour colle	not available	0853347	BAXTER SA	LU

TISSEEL S/D 4 ml Solutions pour colle	not available	0853351	BAXTER SA	LU
TISSEEL S/D 10 ml Solutions pour colle	not available	0853333	BAXTER SA	LU
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
TISSEEL S/D 10 ml Solutions pour colle	not available	0702664	BAXTER SA	LU
Tisseel	not available	41378	BAXTER A/S	DK
TISSEEL Ready to use Solutions for Sealant	not available	PL 00116/0627	BAXTER HEALTHCARE LTD.	XI
TISSEEL Lyo Two- Component Fibrin Sealant	not available	PL 00116/0321	BAXTER HEALTHCARE LTD.	XI

Tisseellyo, associação, pó e solvente para cola para tecidos	not available	5043542	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 Lyo prašci i otapala za tkivno ljepilo	not available	HR-H-488638383	BAXTER 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 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 weefsellijm	not available	BE403611	BAXTER SA	BE
TISSEEL S/D 10 ml Oplossingen voor weefsellijm	not available	BE403627	BAXTER SA	BE