

Annex I

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

Aprotinin containing medicinal products with Marketing Authorisation in the European Union

Member State (EU/EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
AT - Austria	Bayer Austria GmbH Herbststraße 6-10 A-1160 Wien Austria	TrasyloI 10.000 KIE/ml - Infusionsflasche	10.000 KIU/ml	solution for infusion	intravenous use
BE-Belgium	Belgium Bayer S.A. 14, J.E. Mommaertsiaan B- 1831 Diegem Belgium	TrasyloI	10.000 KIU/ml	solution for infusion	intravenous use
CZ - Czech Republic	Chemical Works of Gedeon Richter Plc., HU-1103 Budapest, Gyömrői út 19-21., Hungary	Gordox	10 ku/ml	solution for injection	intravenous use
CZ - Czech Republic	Bayer Schering Pharma AG Mullerstrasse 178 13353 Berlin Germany	TrasyloI 500 000 KIE	10 ku/ml	solution for infusion	intravenous use
DE - Germany	Bayer Pharma Aktiengesellschaft registered business address: Müllerstr. 178 D-13353 Berlin postal address: D-13342 Berlin	Trasynin 0,5	70.0 mg /50 ml	solution for infusion	intravenous use

DE - Germany	Bayer Pharma Aktiengesellschaft registered business address: Müllerstr. 178 D-13353 Berlin postal address: D-13342 Berlin	Trasynin 1,0	140.0 mg /100 ml	solution for infusion	intravenous use
DE - Germany	Bayer Pharma Aktiengesellschaft registered business address: Müllerstr. 78 D-13353 Berlin postal address: D-13342 Berlin	Trasynin 2,0	280.0 mg /200 ml	solution for infusion	intravenous use
DE - Germany	Bayer Vital GmbH D-51373 Leverkusen	Trasylool 0,5	70.0 mg /50 ml	solution for infusion	intravenous use
DE - Germany	Bayer Vital GmbH D-51373 Leverkusen	Trasylool 1,0	140.0 mg /100 ml	solution for infusion	intravenous use
DE - Germany	Bayer Vital GmbH D-51373 Leverkusen	Trasylool 2,0	280.0 mg /200 ml	solution for infusion	intravenous use
DK - Denmark	Bayer Schering Pharma AG, Müllerstrasse 170-178, DE- 13342 Berlin, Germany	Trasylool	10.000 KIE/ml	solution for injection	intravenous use

EL - Greece	Bayer Hellas AG 18 - 20 , Sorou Str. 151 25 , Marousi - Athens	TRASYLOL	500000 KIU/50ML	solution for infusion	intravenous use
ES - Spain	QUIMICA FARMACEUTICA BAYER, S.L Av. Baix Llobregat, 3-5 08970 Sant Joan Despi Barcelona - España	TRASYLOL SOLUCIÓN PARA PERFUSIÓN INTRAVENOSA	10.000 K10.000 KIU/ml IU/ml	solution for perfusion	intravenous use
FI - Finland	Bayer HealthCare AG, 51368 Leverkusen, Germany	TRASYLOL	10 000 KIU/ml	solution for injection/infusion	intravenous use
FR - France	BAYER SANTE - 220, avenue de la recherche - 59120 LOOS	TrasyloI	1 000 000 KUI/100 mL	solution for injection	intravenous use
FR - France	BAYER SANTE - 220, avenue de la recherche - 59120 LOOS	TrasyloI	2 000 000 KUI/200 mL	solution for injection	intravenous use
FR - France	BAYER SANTE - 220, avenue de la recherche - 59120 LOOS	TrasyloI	500 000 UIK/50 mL	solution for injection	intravenous use
HU - Hungary	Richter Gedeon Nyrt. Gyömrői út 19-21. 1103 Budapest, Hungary	Gordox	100 000 KIU/10 ml	solution for injection	intravenous use

HU - Hungary	Richter Gedeon Nyrt. Gyömrői út 19-21. 1103 Budapest, Hungary	Gordox	500 000 KIU/50 ml	solution for infusion	intravenous use
HU - Hungary	Bayer Healthcare AG Kaiser-Wilhelm-Allee, Bldg. E39 51368 Leverkusen, Germany	Trasylol	500 000 KIU/50 ml	solution for infusion	intravenous use
LU - Luxembourg	Bayer S.A. 14, J.E. Mommaertslaan B- 1831 Diegem	TRASYLOL	50.000U/50ml	solution for injection	intravenous use
LV - Latvia	Gedeon Richter Ltd. Gyomroi ut 19-21 Budapest HU-1103 Hungary	Gordox 10 000 KSV/ml šķīdums infūzijām	10 000 KIU/ml	solution for infusion	intravenous use
MT - Malta	Bayer Plc Bayer House Strawberry Hill Newbury Berkshire RG14 1JA United Kingdom trading as Bayer Plc, Pharmaceutical division	TRASYLOL	10000KIU/ML	solution for infusion	intravenous use
NL - Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht The Netherlands	Trasylol 500.000, oplossing voor infusie 10.000 KIE/ml	10.000 KIU/ml	solution for infusion	intravenous use

PL - Poland	Bayer Pharma AG Berlin, D-13342 Germany		Trasyloł	555,6 Ph.Eur.u. (1 000 000 KIU)	solution for infusion	intravenous use
PL - Poland	Bayer Pharma AG Berlin, D-13342 Germany		Trasyloł	1111,1 Ph.Eur.u. (2 000 000 KIU)	solution for infusion	intravenous use
PL - Poland	Bayer Pharma AG Berlin, D-13342, Germany		Trasyloł	277,8 j. Ph. Eur. (500 000 KIU)	solution for infusion	intravenous use
PT - Portugal	Bayer Portugal, S.A. Quinta do Pinheiro 5 2794-003 Carnaxide Portugal	Rua	Trasyloł	500000 U.I.C/50 ml	solution for infusion	intravenous use
PT - Portugal	Bayer Portugal, S.A. Quinta do Pinheiro 5 2794-003 Carnaxide Portugal	Rua	Trasyloł 1.000.000 UIC	1000000 U.I.C/100 ml	solution for infusion	intravenous use
PT - Portugal	Bayer Portugal, S.A. Quinta do Pinheiro 5 2794-003 Carnaxide Portugal	Rua	Trasyloł 2.000.000 UIC	2000000 U.I.C/200 ml	solution for infusion	Intravenous use
SE - Sweden	Bayer Schering Pharma AG Müllerstrasse 178 DE-133 42 Berlin Germany		Trasyloł	10000 KIE/ml	solution for injection/infusion	intravenous use

SK - Slovakia	Richter Gedeon Nyrt., Budapest 10, H-1475 Hungary Pf. 27.,	GORDOX	100 000 IU/10 ml	solution for injection	intravenous use
SL - Slovenia	Bayer d.o.o., Bravničarjeva 13, Ljubljana, Slovenia	TRASYLOL	10 000 KIU/ml	solution for injection and infusion	intravenous use
UK - United Kingdom	Bayer plc Bayer House Strawberry Hill Newbury, Berkshire RG14 1JA UK	Trasylol Solution	10,000 KIU/ML	solution for injection	intravenous use
UK - United Kingdom	Nordic Pharma Limited, Abbey House, 1650 Arlington Business Park, Theale, Reading, Berkshire RG7 4SA, UK	Aprotinin 10,000 KIU/ml Injection	10,000 KIU/ml	solution for injection	intravenous use