

Annex I

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

Tranexamic acid 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	Pfizer Corporation Austria GmbH Floridsdorfer Hauptstraße 1 A-1210 Wien Austria	Cyklokapron - Ampullen	0,5 g/5 ml	Solution for injection	intravenous use
BE - Belgium	PFIZER S.A.N.V. Bld de la Plaine 17 1050 Brussels Belgium	Cyklokapron	100 mg/5 ml	Solution for injection	intravenous use
BE - Belgium	Eumedica S.A. Winston Churchillaan 67 1180 Brussels Belgium	Exacyl 500	500 mg/5 ml	Solution for injection	intravenous use
CY - Cyprus	MEDOCHEMIE LTD, 1-10 CONSTANTINOUPOLEOS STREET, P.O.BOX 51409, 3505 LEMESOS, CYPRUS	AZEPTIL INJECTION 500MG/5ML	500MG/5ML	INJECTION	intravenous use
CY - Cyprus	MEDOCHEMIE LTD, 1-10 CONSTANTINOUPOLEOS STREET, P.O.BOX 51409, 3505 LEMESOS, CYPRUS	AZEPTIL INJECTION 250MG/5ML	250MG/5ML	INJECTION	intravenous use

CZ - Czech Republic	Sanofi-Aventis, s.r.o., Evropská 846/176a, 160 00 Praha 6, Czech Republic	Exacyl	100 mg/ml	Solution for injection	intravenous use
DE - Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin	Cyklokapron- Injektionslösung	500mg /5ml	Solution for injection	intravenous use
DK - Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Tranexamsyre "Pfizer"	100 mg/ml	Solution for injection	intravenous use
EL - Greece	A. NIKOLAKOPOULOS A.E. GALATSIU AVENUE 115, Athens 11146	TRANSAMIN	500MG/5ML	Solution for Injection or infusion	intravenous use
ES - Spain	ROTTAPHARM S.L. Avda. Diagonal 67-69 08019 Barcelona España	AMCHAFIBRIN 500 mg SOLUCIÓN INYECTABLE	500mg/5 ml	solution for injection	intravenous use

ET - Estonia	Pfizer Enterprises SARL Round-Point du Kirchberg 51, Avenue J.F. Kennedy L-1855 Luxembourg	CYKLOKAPRON	100mg/ml	solution for injection	intravenous use
FI - Finland	Oy Leiras Finland Ab Paciuksenkatu 21 PL 1406 00101 Helsinki Finland	CAPRILON	100 mg/ml	Solution for injection	intravenous use
FR - France	Sanofi Aventis France 1-13, bd Romain Rolland 75014 Paris France	Exacyl 0,5 g/5 ml I.V., solution injectable	0,5 g/5 ml	solution for injection	intravenous use
HU - Hungary	sanofi-aventis Zrt. Tó u. 1-5. 1045 Budapest, Hungary	Exacyl	0,5g/5ml	solution for injection	intravenous use
IE - Ireland	Pharmacia Ireland Ltd, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 Ireland	Cyklokapron 500mg/5ml solution for injection or infusion	100mg/ml	Solution for injection	intravenous use

IS - Iceland	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Tranexamsyre "Pfizer"	100 mg/ml	Solution for injection	intravenous use
IT - Italy	Rottapharm S.p.A. Via Valosa di Sopra, 9 20052 Monza - Italy	UGUROL	500 mg/5 ml	solution for injection	intravenous use
IT - Italy	Istituto Farmacobiologico Malesci S.p.A. Via Lungo l'Emma 7 50015 Bagno a Ripoli (Firenze) Italy	TRANEX	500 mg/5 ml	solution for injection	intravenous use
IT - Italy	Bioindustria Laboratorio Italiano Medicinali spa Via De Ambrosiis, 2 15067 Novi Ligure Alessandria Italy	ACIDO TRANEXAMICO BIOINDUTRIA L.I.M.	500 mg/5 ml	solution for injection	intravenous use
LU - Luxembourg	Eumedica SA 67, Avenue Winston Churchill B- 1180 Bruxelles	EXACYL	500mg/5ml	solution for injection	intravenous use
LU - Luxembourg	PFIZER S.A.N.V. Bld de la Plaine 17 1050 Brussels Belgium	Cyklokapron	100 mg/ml	Solution for injection	Intravenous use

NL - Netherlands	Pfizer B.V. Rivium Westlaan 142 2909 LD, Capelle a/d IJssel	Cyklokapron, oplossing voor injectie 100 mg/ml	100 mg/ml	solution for injection	intravenous use
NO - Norway	Pfizer AS Postboks 3 1324 Lysaker Norway	CYKLOKAPRON	100mg/ml	injection for solution	intravenous use
PL - Poland	Warszawskie Zakłady Farmaceutyczne POLFA S.A. 22/24 karolkowa st. 01-207 Warsaw, Poland	Exacyl	100 mg/ml	solution for infusion	intravenous use
PL - Poland	Sanofi-Aventis France Boulevard Romain Rolland 1- 13, F-75014 Paris, France	Exacyl	100 mg/ml	solution for infusion	intravenous use
SE - Sweden	Pfizer AB 191 90 Sollentuna Sweden	Cyklokapron	100mg/ml	Solution for injection	intravenous use
UK - United Kingdom	Pharmacia Limited Walton Oaks, Dorking Road, Tadworth Surrey KT20 7NS United Kingdom	CYKLOKAPRON INJECTION 500MG/ML	500mg/ml	Solution for Injection	intravenous use