

ANNEX I

**LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE
MEDICINAL PRODUCTS, ROUTES OF ADMINISTRATION, MARKETING
AUTHORISATION HOLDERS IN THE MEMBER STATES**

Member State EU/EEA	Marketing Authorisation Holder	(Invented) Name	Strength	Pharmaceutical Form	Route of administration	Content concentration
Austria	Roche Austria GmbH, Engelhornngasse 3, 1211 Wien Austria	Kytril 3 mg - Injektionslösung	3 mg/3 ml	Solution for injection	Intravenous use	3 ml
Austria	Roche Austria GmbH, Engelhornngasse 3, 1211 Wien Austria	Kytril 2 mg - Filmtabletten	2 mg	Film-coated tablet	Oral use	
Belgium	N.V. Roche S.A. Rue Dante 75 1070 Bruxelles Belgium	Kytril 1 mg/1 ml solution injectable	1 mg	Solution for injection	Intravenous use	1 mg/1 ml
Belgium	N.V. Roche S.A. Rue Dante 75 1070 Bruxelles Belgium	Kytril 3 mg/3 ml solution injectable	3 mg	Solution for injection	Intravenous use	3 mg/3 ml
Belgium	N.V. Roche S.A. Rue Dante 75 1070 Bruxelles Belgium	Kytril 1 mg comprimés pelliculés	1 mg	Film-coated tablet	Oral use	
Bulgaria	Roche Bulgaria EOOD, 16 Bialo Pole Str. 1618 Sofia Bulgaria	Kytril	1 mg / ml	Solution for injection/infusion	Intravenous use	1 ml (1 mg/ ml) 3 ml (1 mg/ ml)
Bulgaria	Roche Bulgaria EOOD, 16 Bialo Pole Str. 1618 Sofia Bulgaria	Kytril	2 mg	Film-coated tablet	Oral use	
Czech Republic	Roche s.r.o., Dukelských hrdinů 52 170 00 Praha 7 Czech Republic	Kytril 2 mg	2 mg	Film-coated tablet	Oral use	
Czech Republic	Roche s.r.o., Dukelských hrdinů 52 170 00 Praha 7 Czech Republic	Kytril inj./inf	1 mg/ml	Solution for injection/infusion	Intravenous use	1 mg/1 ml

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Estonia	Roche Eesti OÜ Lõõtsa 2, 11415 Tallinn Estonia	Kytril	1mg/ml	Concentrate for solution for injection/infusion	Intravenous use	1mg/ml (1ml and 3ml)
Estonia	Roche Eesti OÜ Lõõtsa 2, 11415 Tallinn Estonia	Kytril	1mg	Film-coated tablet	Oral use	
Finland	Roche Oy PL 12 02181 Espoo Finland	Kytril	1 mg	Film-coated tablet	Oral use	
Finland	Roche Oy PL 12 02181 Espoo Finland	Kytril	2 mg	Film-coated tablet	Oral use	
Finland	Roche Oy PL 12 02181 Espoo Finland	Kytril	1 mg/ml	Solution for injection	Intravenous use	5x1 ml and 5x3 ml
France	ROCHE 52 Boulevard du Parc 92521 NEUILLY SUR SEINE cedex France	Kytril 3mg/3ml solution injectable pour voie intraveineuse	3mg/3ml	Solution for injection	Intravenous use	3mg/3ml
France	ROCHE 52 Boulevard du Parc 92521 NEUILLY SUR SEINE cedex France	Kytril 1mg/ comprimé pelliculé	1 mg	Film-coated tablet	Oral use	
France	ROCHE 52 Boulevard du Parc 92521 NEUILLY SUR SEINE cedex France	Kytril 2 mg comprimé pelliculé	2 mg	Film-coated tablet	Oral use	

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Germany	Roche Pharma AG Emil-Barell-Straße 1 79639 Grenzach-Wyhlen Germany	Kevatril 1 mg/1 ml Injektionslösung	1 mg	Solution for injection	Intravenous use	1 ml
Germany	Roche Pharma AG Emil-Barell-Straße 1 79639 Grenzach-Wyhlen Germany	Kevatril Filmtabletten 2 mg	2 mg	Film-coated tablet	Oral use	
Germany	Roche Pharma AG Emil-Barell-Straße 1 79639 Grenzach-Wyhlen Germany	Kevatril 3 mg/3 ml Injektionslösung	3 mg	Solution for injection	Intravenous use	3 ml
Greece	Roche (Hellas) A.E. Alamanas 4 & Delfon, 15125 Maroussi Greece	Kytril	1mg	Film-coated tablet	Oral use	
Greece	Roche (Hellas) A.E. Alamanas 4 & Delfon, 15125 Maroussi Greece	Kytril	2 mg	Film-coated tablet	Oral use	
Greece	Roche (Hellas) A.E. Alamanas 4 & Delfon, 15125 Maroussi Greece	Kytril	1mg/1ml	Solution for injection	Intravenous use	1mg/1ml
Greece	Roche (Hellas) A.E. Alamanas 4 & Delfon, 15125 Maroussi Greece	Kytril	3mg/3ml	Solution for injection	Intravenous use	3mg/3ml
Hungary	Roche (Hungary) Ltd H-2040 Budaörs Edison u. 1. Hungary	Kytril	1 mg	Film-coated tablet	Oral use	

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Hungary	Roche (Hungary) Ltd H-2040 Budaörs Edison u. 1. Hungary	Kytril	3 mg/3 ml	Solution for injection	Intravenous use	3 mg/3 ml
Ireland	Roche Products Limited, 6 Falcon Way, Shire Park Welwyn Garden City AL7 1TW, United Kingdom	Kytril Tablets 1mg	1mg	Film-coated tablet	Oral use	
Ireland	Roche Products Limited, 6 Falcon Way, Shire Park Welwyn Garden City AL7 1TW, United Kingdom	Kytril Tablets 2mg	2mg	Film-coated tablet	Oral use	
Ireland	Roche Products Limited, 6 Falcon Way, Shire Park Welwyn Garden City AL7 1TW, United Kingdom	Kytril Ampoules 1 mg/1 ml concentrate for solution for infusion or injection	1mg/1ml	Concentrate for solution for infusion/injection	Intravenous use	1ml contains 1mg granisetron (hydrochloride) 1mg contains 9mg sodium chloride = 3.54 mg sodium
Ireland	Roche Products Limited, 6 Falcon Way, Shire Park Welwyn Garden City AL7 1TW, United Kingdom	Kytril Infusion 3 mg/3 ml concentrate for solution for infusion or injection	3mg/3ml	Concentrate for solution for infusion/injection	Intravenous use	3ml contains 3mg granisetron (hydrochloride) 3ml contains 27mg sodium chloride = 10.62 mg sodium
Italy	Roche S.p.A. Piazza Durante 11 20131 Milano Italy	Kytril	3 mg/3 ml	Solution for injection	Intravenous use	3 mg/3 ml
Italy	Roche S.p.A. Piazza Durante 11 20131 Milano Italy	Kytril	1 mg/1 ml	Solution for injection	Intravenous use	1 mg/1 ml
Italy	Roche S.p.A. Piazza Durante 11 20131 Milano Italy	Kytril	3 mg/5 ml	Solution for injection	Intravenous use	3 mg/5 ml

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Italy	Roche S.p.A. Piazza Durante 11 20131 Milano Italy	Kytril	1 mg	Film-coated tablet	Oral use	
Italy	Roche S.p.A. Piazza Durante 11 20131 Milano Italy	Kytril	2 mg	Film-coated tablet	Oral use	
Latvia	Roche Latvija SIA G. Astras 8b Riga, LV-1082 Latvia	Kytril 1 mg/ml solution for injection	1 mg/ml	Solution for injection	Intravenous use	1 mg/ml
Latvia	Roche Latvija SIA G. Astras 8b Riga, LV-1082 Latvia	Kytril 1 mg film-coated tablets	1 mg	Film-coated tablet	Oral use	
Lithuania	UAB "Roche Lietuva" J. Jasinskio 16b, LT-01112 Vilnius Lithuania	Kytril	1mg	Film-coated tablet	Oral use	
Lithuania	UAB "Roche Lietuva" J. Jasinskio 16b, LT-01112 Vilnius Lithuania	Kytril	1mg/ml	Solution for injection/infusion	Intravenous use	1 mg/1 ml
Lithuania	UAB "Roche Lietuva" J. Jasinskio 16b, LT-01112 Vilnius Lithuania	Kytril	3mg/3ml	Solution for injection/infusion	Intravenous use	3 mg/3 ml
Luxembourg	N.V. Roche S.A. Rue Dante 75 1070 Bruxelles Belgium	Kytril 1 mg/1 ml solution injectable	1 mg	Solution for injection	Intravenous use	1 mg/1 ml
Luxembourg	N.V. Roche S.A. Rue Dante 75 1070 Bruxelles Belgium	Kytril 3 mg/3 ml solution injectable	3 mg	Solution for injection	Intravenous use	3 mg/3 ml

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Luxembourg	N.V. Roche S.A. Rue Dante 75 1070 Bruxelles Belgium	Kytril 1 mg comprimés pelliculés	1 mg	Film-coated tablet	Oral use	
Malta	Roche Products Limited, 6 Falcon Way, Shire Park Welwyn Garden City AL7 1TW, United Kingdom	Kytril Tablets 1mg	1mg	Film-coated tablet	Oral use	
Malta	Roche Products Limited, 6 Falcon Way, Shire Park Welwyn Garden City AL7 1TW, United Kingdom	Kytril Injection 3mg/3ml	3mg/3ml	Concentrate for solution for infusion/injection	Intravenous use	1ml contains 1mg granisetron (hydrochloride)
Netherlands	Roche Nederland B.V., Postbus 44, 3440 AA Woerden Netherlands	Kytril i.v. 3 mg = 3 ml, oplossing voor injectie 1 mg/ml	1 mg/ml	Solution for injection	Intravenous use	1 mg/ml
Netherlands	Roche Nederland B.V., Postbus 44, 3440 AA Woerden Netherlands	Kytril i.v. 1 mg = 1 ml, oplossing voor injectie 1 mg/ml	1 mg/ml	Solution for injection	Intravenous use	1 mg/ml
Netherlands	Roche Nederland B.V., Postbus 44, 3440 AA Woerden Netherlands	Kytril 1 mg tabletten, omhulde tabletten	1 mg	Film-coated tablet	Oral use	
Netherlands	Roche Nederland B.V., Postbus 44, 3440 AA Woerden Netherlands	Kytril 2 mg tabletten, omhulde tabletten	2 mg	Film-coated tablet	Oral use	
Portugal	Roche Farmacêutica Química, Lda Estrada nacional 249-1, 2720-413, Amadora Portugal	Kytril	1 mg	Film-coated tablet	Oral use	
Portugal	Roche Farmacêutica Química, Lda Estrada nacional 249-1, 2720-413, Amadora Portugal	Kytril	2 mg	Film-coated tablet	Oral use	

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Portugal	Roche Farmacêutica Química, Lda Estrada nacional 249-1, 2720-413, Amadora Portugal	Kytril	1 mg/1 ml	Solution for injection	Intravenous use	1 ml (1 mg/1 ml)
Portugal	Roche Farmacêutica Química, Lda Estrada nacional 249-1, 2720-413, Amadora Portugal	Kytril	3 mg/3 ml	Solution for injection	Intravenous use	3 ml (3 mg/3 ml)
Romania	Roche Romania SRL 9-9A Dimitrie Pompei Street, Building 19, Entrance B, 3rd Floor, Sector (District) 2, Bucharest Romania	Kytril 1 mg	1 mg	Film-coated tablet	Oral use	
Romania	Roche Romania SRL 9-9A Dimitrie Pompei Street, Building 19, Entrance B, 3rd Floor, Sector (District) 2, Bucharest Romania	Kytril	3mg/3ml	Solution for injection	Intravenous use	3mg/3ml (1mg/ml)
Slovak Republic	Roche Slovensko s.r.o. Cintorínska 3/A Bratislava Slovak Republic	Kytril 1 mg	1 mg	Film-coated tablet	Oral use	
Slovak Republic	Roche Slovensko s.r.o. Cintorínska 3/A Bratislava Slovak Republic	Kytril 2 mg	2 mg	Film-coated tablet	Oral use	
Slovak Republic	F.Hoffmann-La Roche Ltd. Basel, Switzerland	Kytril INJ/INF	1 mg/1 ml	Concentrate for solution for infusion/injection	Intravenous use	1 mg/1 ml
Slovenia	Roche farmacevtska družba d.o.o. Vodovodna cesta 109 1000 Ljubljana Slovenia	Kytril 2 mg filmsko obložene tablete	2 mg	Film-coated tablet	Oral use	

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Slovenia	Roche farmacevtska družba d.o.o. Vodovodna cesta 109 1000 Ljubljana Slovenia	Kytril 1 mg/1 ml raztopina za injiciranje	1 mg/1 ml	Solution for injection	Intravenous use	1 mg/ml
Slovenia	Roche farmacevtska družba d.o.o. Vodovodna cesta 109 1000 Ljubljana Slovenia	Kytril 3 mg/3 ml raztopina za injiciranje	3 mg/3 ml	Solution for injection	Intravenous use	1 mg/ml
Spain	Roche Farma S.A. C/ Eucalipto 33 28016 Madrid Spain	Kytril 1 mg comprimidos recubiertos con película	1 mg	Film-coated tablet	Oral use	
Spain	Roche Farma S.A. C/ Eucalipto 33 28016 Madrid Spain	Kytril 1 mg/1 ml solución inyectable	1mg/1ml	Solution for injection	Intravenous use	1 mg/ml
Spain	Roche Farma S.A. C/ Eucalipto 33 28016 Madrid Spain	Kytril 3 mg/3 ml solución inyectable	3mg/3ml	Solution for injection	Intravenous use	1 mg/ml
Sweden	Roche AB Box 47327 100 74 Stockholm Sweden	Kytril	1 mg	Film-coated tablet	Oral use	
Sweden	Roche AB Box 47327 100 74 Stockholm Sweden	Kytril	2 mg	Film-coated tablet	Oral use	
Sweden	Roche AB Box 47327 100 74 Stockholm Sweden	Kytril	1 mg/ml	Solution for injection	Intravenous use	5 x 1 ml 5 x 3 ml

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United Kingdom	Roche Products Limited, 6 Falcon Way, Shire Park Welwyn Garden City AL7 1TW United Kingdom	Kytril Tablets 1mg	1mg	Film-coated tablet	Oral use	
United Kingdom	Roche Products Limited, 6 Falcon Way, Shire Park Welwyn Garden City AL7 1TW United Kingdom	Kytril Tablets 2mg	2mg	Film-coated tablet	Oral use	
United Kingdom	Roche Products Limited, 6 Falcon Way, Shire Park Welwyn Garden City AL7 1TW United Kingdom	Kytril Ampoule 1mg/1ml	1mg/1ml	Concentrate for solution for infusion/injection	Intravenous use	1ml contains 1mg granisetron (hydrochloride)
United Kingdom	Roche Products Limited, 6 Falcon Way, Shire Park Welwyn Garden City AL7 1TW United Kingdom	Kytril Infusion 3mg/ml	3mg/3ml	Concentrate for solution for infusion/injection	Intravenous use	1mg of granisetron per 1 ml solution