

## **Annex I**

*List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the Member States*

<u>Member State EU/EEA</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Austria	Merck Sharp & Dohme Ges.m.b.H. Am Euro Platz 2 1120 Wien Austria	Zienam 500 mg Trockensubstanz zur Infusionsbereitung	500 mg	Powder for solution for infusion	Intravenous use
Belgium	Merck Sharp & Dohme B.V. Chaussée de Waterloo 1135 1180 Bruxelles Belgium	Tienam 500 mg, poudre pour solution pour perfusion / Tienam Monovial 500 mg, poudre pour solution pour perfusion	500 mg/500 mg	Powder for solution for infusion	Intravenous use
Bulgaria	Merck Sharp & Dohme Bulgaria EOOD 55, Nikola Vaptzarov Blvd., Expo 2000 Sofia 1407 Bulgaria	Tienam 500/500 mg powder for solution for infusion Тиенам 500/500 mg прах за инфузионен разтвор	500/500mg	Powder for solution for infusion	Intravenous use
Czech Republic	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, The Netherlands	Tienam i.v. 500mg /500mg i.v.	500 mg/500 mg	Powder for solution for infusion	Intravenous use
Estonia	Merck Sharp & Dohme OÜ Peterburi St 46, 11415 Tallinn Estonia	TIENAM I.V. 500 MG/500 MG	500 mg/500 mg	Powder for solution for infusion	Intravenous use
Finland	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, The Netherlands	TIENAM	500 mg/ 500 mg	Powder for solution for infusion	Intravenous use
France	Merck Sharp & Dohme Chibret 3 avenue Hoche 75114 Paris cedex 08 France	TIENAM 500 mg/500 mg, poudre pour perfusion avec système de transfert pour poche	500 mg/500 mg	Powder for infusion	Intravenous use
France	Merck Sharp & Dohme Chibret 3 avenue Hoche 75114 Paris cedex 08 France	TIENAM 250 mg/250 mg, poudre pour perfusion	250 mg/250 mg	Powder for infusion	Intravenous use

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France	Merck Sharp & Dohme Chibret 3 avenue Hoche 75114 Paris cedex 08 France	TIENAM 500 mg/500 mg, poudre pour perfusion	500 mg/500 mg	Powder for infusion	Intravenous use
France	Merck Sharp & Dohme Chibret 3 avenue Hoche 75114 Paris cedex 08 France	TIENAM 500 mg/500 mg, poudre et solution pour usage parentéral (IM)	500 mg/500 mg	Powder for suspension for parenteral use (IM)	Intramuscular use
Germany	MSD SHARP & DOHME GMBH Lindenplatz 1 D-85540 Haar Germany	ZIENAM° 500 mg Pulver zur Herstellung einer Infusionslösung	500 mg/500 mg	Powder for solution for infusion	Intravenous use
Greece	Vianex S.A Tatoiou str. 18 <sup>th</sup> Km Athens-Lamia National Road 14671 Nea Erythrea Greece	Primaxin DR.PD.INJ (500+500)mg/Vial (IV)	500 mg	Dry Powder for injection	Intravenous use
Greece	Vianex S.A Tatoiou str. 18 <sup>th</sup> Km Athens-Lamia National Road 14671 Nea Erythrea Greece	Primaxin DR.PD.INJ (250+250mg/Vial (IV)	250mg	Dry Powder for injection	Intravenous use
Hungary	MSD Hungary Ltd. 1123 Budapest, Alkotás u. 50. Hungary	Tienam	500 mg	Powder for solution for infusion	Intravenous infusion
Iceland	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, P.O.Box 581, 2003 PC Haarlem The Netherlands	Tienam	500 mg/500 mg	Powder for solution for infusion	Intravenous infusion

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Ireland	Merck Sharp & Dohme Ireland (Human Health) Limited Pelham House South County Business Park Leopardstown Dublin 18 Ireland	Primaxin IV 500mg/500mg Powder for Solution for Infusion	500 mg/500 mg	Powder for solution for infusion	Intravenous infusion
Italy	Merck Sharp & Dohme (Italia) S.p.A. Via Vitorchiano, 151 - 00189 Roma Italy	TIENAM (20 ml)	500 mg/500 mg	Powder for solution for infusion	Intravenous infusion
Italy	Merck Sharp & Dohme (Italia) S.p.A. Via Vitorchiano, 151 - 00189 Roma Italy	IMIPEM (20 ml)	500 mg/500 mg	Powder for solution for infusion	Intravenous infusion
Italy	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A, Viale Shakespeare, 47 00144 Roma Italy	TENACID (20 ml)	500 mg/500 mg	Powder for solution for infusion	Intravenous infusion
Latvia	SIA "Merck Sharp & Dohme Latvija", Skanstes 13, Riga, LV-1013 Latvia	TIENAM I.V.	500 mg/500 mg	Powder for solution for infusion	Intravenous use

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Lithuania	Merck Sharp & Dohme, UAB, Kęstučio 59/27, LT-08124 Vilnius Lithuania	TIENAM I.V.	500 mg + 500 mg	Powder for solution for injection	Intravenous use
Luxembourg	Merck Sharp & Dohme B.V. Chaussée de Waterloo 1135 1180 Bruxelles Belgium	Tienam 500 mg, poudre pour solution pour perfusion / Tienam Monovial 500 mg, poudre pour solution pour perfusion	500 mg/500 mg	Powder for solution for infusion	Intravenous use
Malta	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU United Kingdom	Primaxin IV 500mg Injection	500mg	Powder for concentrate for solution for infusion	Intravenous use
Netherlands	Merck Sharp & Dohme BV Waarderweg 39 2031 BN Haarlem The Netherlands	Tiënam I.V.	250 mg and 500 mg	Powder for solution for infusion	Intravenous use
Norway	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem, P.O.Box 581, 2003 PC Haarlem The Netherlands	Tienam	500 mg/500 mg	Powder for solution for infusion	Intravenous use
Poland	MSD Polska Sp. z o.o. ul. Chłodna 51 00-867 Warszawa Poland	TIENAM	500 mg/500 mg	Powder for solution for infusion	Intravenous use
Portugal	Merck Sharp & Dohme, Lda. Quinta da Fonte Edifício Vasco da Gama, 19 P.O. BOX 214 Porto Salvo 2770-192 Paço de Arcos Portugal	Tienam IV	500 mg / 500 mg	Powder for solution for infusion	Intravenous use

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Romania	Merck Sharp & Dohme Romania S.R.L. Bucharest Business Park, Șos. București-Ploiești Nr.1A, Clădirea C1, Etaj 3, Sector 1, București Romania	TIENAM I.V., pulbere pentru soluție perfuzabilă	500 mg/500 mg	Powder for solution for infusion	Intravenous use
Slovak Republic	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem P.O. Box 581, 2003 PC Haarlem The Netherlands	TIENAM i.v.	500 mg/500 mg	Powder for solution for infusion	Intravenous use
Slovenia	Merck Sharp & Dohme, inovativna zdravila d.o.o. Šmartinska cesta 140, 1000 Ljubljana, Slovenia	CONET 500 mg/500 mg prašek za raztopino za infundiranje	500 mg/500 mg	Powder for solution for infusion	Intravenous use
Spain	Merck Sharp & Dohme de España, S.A. C/ Josefa Valcárcel, 38 28027 Madrid Spain	TIENAM I.V. 500 mg powder for solution for infusion	500 mg/500 mg	Powder for solution for infusion	Intravenous use
Sweden	Merck Sharp & Dohme B.V. Waarderweg 39, Haarlem, P.O.Box 581, 2003 PC Haarlem The Netherlands	Tienam	500 mg/ 500 mg	Powder for solution for infusion	Intravenous use
United Kingdom	Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Herts, EN11 9BU United Kingdom	PrimaxinIV 500mg Injection	500mg	Powder for concentrate for solution for infusion	Intravenous use