



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 February 2018
EMA/88494/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal

Active substance: cilastatin / imipenem

Procedure no.: PSUSA/00000748/201706



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
TIENAM® 500 mg/500 mg, Pulver zur Herstellung einer Infusionslösung	NL/H/2160/001	BE135606	MSD BELGIUM BVBA/SPRL	BE
TIENAM 500 mg/500 mg σκόνη για διάλυμα προς έγχυση	NL/H/2160/001	21719	MERCK SHARP & DOHME BV	CY
TIENAM 500 mg/500 mg pulver till infusionsvätska, lösning	NL/H/2160/001	9375	MERCK SHARP & DOHME BV	FI
TIENAM 500 mg/500 mg por oldatos infúzióhoz	NL/H/2160/001	OGYI-T-1538/05	MSD PHARMA HUNGARY KFT.	HU
TIENAM 500 mg/500 mg por oldatos infúzióhoz	NL/H/2160/001	OGYI-T-1538/04	MSD PHARMA HUNGARY KFT.	HU
TIENAM I.V. 500 mg/500 mg milteliai infuziniam tirpalui	NL/H/2160/001	LT/1/93/2969/002	MERCK SHARP & DOHME, UAB	LT
TIENAM I.V. 500 mg/500 mg milteliai infuziniam tirpalui	NL/H/2160/001	LT/1/93/2969/003	MERCK SHARP & DOHME, UAB	LT
TIENAM 500 mg/500 mg prašek za raztopino za infundiranje	NL/H/2160/001	H/93/00417/001	MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O.	SI
TIENAM I.V. 500 mg/500 mg, infusioonilahuse pulber	NL/H/2160/001	090094	MERCK SHARP & DOHME OU	EE
Tienam 500 mg/500 mg pulver til infusjonsvæske, oppløsning	NL/H/2160/001	00-7308	MERCK SHARP & DOHME BV	NO
TIENAM 500 mg/500 mg polvo para solución para perfusión	NL/H/2160/001	57.329	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
TIENAM 500 mg/500 mg, poudre pour solution pour perfusion	NL/H/2160/001	34009 571 937 4 4	MSD FRANCE	FR

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
PRIMAXIN IV 500 mg/500 mg powder for solution for infusion	NL/H/2160/001	PL 00025/0229	MERCK SHARP & DOHME LTD.	UK
Zienam 500 mg/500 mg - Pulver zur Herstellung einer Infusionslösung	NL/H/2160/001	1-18024	MERCK SHARP & DOHME GES.M.B.H.	AT
TIENAM 500 mg/500 mg, poudre pour solution pour perfusion	NL/H/2160/001	34009 383 370 0 6	MSD FRANCE	FR
TIENAM IV 500 mg + 500 mg Pó para solução para perfusão	NL/H/2160/001	5053376	MERCK SHARP & DOHME, LDA.	PT
TIENAM I.V. 500 mg/500 mg milteliai infuziniam tirpalui	NL/H/2160/001	LT/1/93/2969/001	MERCK SHARP & DOHME, UAB	LT
ТИЕНАМ 500 mg/500 mg прах за инфузионен разтвор	NL/H/2160/001	20020312	MERCK SHARP & DOHME BULGARIA EOOD	BG
TIENAM, 500 mg + 500 mg, proszek do sporządzania roztworu do infuzji	NL/H/2160/001	R/0990	MSD POLSKA SP. Z O.O.	PL
TIENAM 500 mg/500 mg poeder voor oplossing voor infusie	NL/H/2160/001	RVG 11089	MERCK SHARP & DOHME BV	NL
Tienam 500 mg/500 mg infuusiokuiva-aine, liuosta varten	NL/H/2160/001	9375	MERCK SHARP & DOHME BV	FI
TIENAM I.V. 500 mg/500 mg pulveris infūziju šķīduma pagatavošanai	NL/H/2160/001	93-0495	MERCK SHARP & DOHME LATVIJA SIA	LV

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ZIENAM® 500 mg/500 mg Pulver zur Herstellung einer Infusionslösung Wirkstoffe: Imipenem und Cilastatin	NL/H/2160/001	4697.01.00	MSD SHARP & DOHME GMBH	DE
TIENAM 500 mg/500 mg por oldatos infúzióhoz	NL/H/2160/001	OGYI-T-1538/03	MSD PHARMA HUNGARY KFT.	HU
PRIMAXIN IV 500 mg/500 mg powder for solution for infusion	NL/H/2160/001	MA 058/00901	MERCK SHARP & DOHME LTD.	MT
TIENAM 500 mg/500 mg pulver till infusionsvätska, lösning	NL/H/2160/001	10339	MERCK SHARP & DOHME BV	SE
TIENAM® 500 mg/500 mg, poudre pour solution pour perfusion	NL/H/2160/001	2006129146	MSD BELGIUM BVBA/SPRL	LU
PRIMAXIN IV 500 mg/500 mg powder for solution for infusion	NL/H/2160/001	PA 1286/019/001	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
TIENAM 500 mg/500 mg polvere per soluzione per infusione	NL/H/2160/001	025887062	MSD ITALIA S.R.L.	IT
TIENAM® 500 mg/500 mg, poeder voor oplossing voor infusie	NL/H/2160/001	BE135606	MSD BELGIUM BVBA/SPRL	BE
TIENAM® 500 mg/500 mg, poudre pour solution pour perfusion	NL/H/2160/001	BE135606	MSD BELGIUM BVBA/SPRL	BE
TIENAM® 500 mg/500 mg i.v. prášek pro infuzní roztok	NL/H/2160/001	15/104/87-A/C	MERCK SHARP & DOHME BV	CZ

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Tienam 500 mg/500 mg prašek za raztopino za infundiranje	NL/H/2160/001	H/93/00417/003	MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O.	SI
Tienam 500 mg/500 mg prašek za raztopino za infundiranje	NL/H/2160/001	H/93/00417/002	MERCK SHARP & DOHME INOVATIVNA ZDRAVILA D.O.O.	SI
TIENAM I.V. 500 mg/500 mg pulbere pentru soluție perfuzabilă	NL/H/2160/001	4955/2012/01	MERCK SHARP & DOHME ROMANIA SRL	RO
TIENAM I.V. 500 mg/500 mg pulbere pentru soluție perfuzabilă	NL/H/2160/001	4955/2012/03	MERCK SHARP & DOHME ROMANIA SRL	RO
TIENAM I.V. 500 mg/500 mg pulbere pentru soluție perfuzabilă	NL/H/2160/001	4955/2012/02	MERCK SHARP & DOHME ROMANIA SRL	RO
TIENAM 500 mg/500 mg powder for solution for infusion	NL/H/2160/001	21719	MERCK SHARP & DOHME BV	CY
TIENAM 500 mg/500 mg, poudre pour solution pour perfusion	NL/H/2160/001	34009 571 938 0 5	MSD FRANCE	FR
PRIMAXIN 500 mg/500 mg σκόνη για διάλυμα προς έγχυση	not available	91867/12/06-07-2016	VIANEX S.A.	GR
TIENAM 500 mg/500 mg prašak za otopinu za infuziju	NL/H/2160/001	HR-H-308882042	MERCK SHARP & DOHME D.O.O.	HR
Имецитин 250 mg/250 mg прах за инфузионен разтвор	UK/H/1704/001	20100618	ACTAVIS GROUP PTC EHF.	BG
Impecin 250 mg/250 mg por oldatos infúzióhoz	UK/H/1704/001	OGYI-T-21662/01-02	ACTAVIS GROUP PTC EHF.	HU