Country	Products	Distributor	Dosing info	Dosing info renal	Children	PK info	Indications	Date of revision
Austria 8. 10. 1962	Colistin Forest - Trockenstechampullen mit Lösungsmittel 1 Trockenstechampulle enthält 78,74 mg (1.000.000 I.E.) Colistinmethansulfonat-Natrium entsprechend 33,3 mg Colistin.	Forest Laboratories Nederland	The daily total dose for all age groups is 60,000-75,000 IU / kg body weight administered in 2-3 doses, equivalent to an approximate dose of 2-5 (-10) Mega/day. In case of susceptible organisms, a dose of 3x1 Mega colistin daily is sufficient. For pathogens with reduced sensitivity, the dose can temporarily be increased up to 150,000 IU / kg body weight (equivalent to 10 Mega for an adult). In obese patients the dose should be calculated according to the ideal body weight (Body Mass Index).	Colistin may be administered in renal impairment only when in case of a vital indication. At about a serum creatinine of 1.3 mg/100 ml colistin accumulates, which may cause further deterioration of renal function up to acute renal failure and severe side effects. Furthermore, it can lead to neurotoxic reactions (eg tingling in the mouth, slurred speech, atactic gait) and neuromuscular blockade with respiratory paralysis. If the use of colistin can not be avoided, the initial dose should be the same as forpatients with normal renal function. The maintenance dose should be reduced as a function of serum creatinine or the dosing interval extended: Only indicated in life threatening diseas: Serum creatinine <1,3mg/100ml: 60.000-75.000 IU/kg/day (daily dose 4,2-5,3 Mega/day) Serum creatinine 1,3-5mg/100ml: 15.000-max 30.000 IU/kg/12h(daily dose 1-2 Mega/day) Serum creatinine>5mg/100ml: 15.000-30.000-max 60.000 IU/kg/every 2nd or 3rd day (daily dose(1)-2-4 Mega/every 2nd or 3rd day or 1 Mega/day anuric patients: single dose (normal dose) with effective concentrations over 5 days	School children (7-12 years) 1 - 2 Mega/day Infants (1-6 years) 0,5 - 1 Mega/day Infants (up to 12 months) 0.25 - 0.5 Mega/day	The penetration in tissues and body fluids is limited, the penetration into CSF is minimal even in case of inflammation. High concentrations in the urine, about 20-40 times higher than in the corresponding serum levels. Plasma protein binding is low (<10%). The serum half-life is 2-3 hours. After intravenous infusion, the drug is eliminated primarily via glomerular filtration. Approx. 60% of the administered dose is excreted unchanged in the urine. 2 - 4 hours after application, the highest concentrationsare reached (approximately 50 micrograms / ml after the administration of 1 mega).	Severe infections caused by gram-negative bacteria, especially Pseudomonas aeruginosa und Acinetobacter baumannii, if other antibiotics are not indicated or not active, e.g. pneumonia, sepsis, meningitis, urinary tract infections.	2012/3
Austria	Colistin Xellia 1 Million I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung	Xellia	Up to 60 kg: 50,000 IU / kg (4 mg / kg) of body weight of up to 75,000 IU / kg (6 mg / kg) over 24 hours. The total daily dose should be administered as three equal doses at 8-hour intervals. Over 60 kg: 1-2 million IU every 8 hour. The standard maximum dose is 6 million IU (480 mg) over 24 hours. Limited pharmacokinetic data from critically ill patients suggest that the use of a loading dose and doses that are higher than standard dose may be appropriate. In severe infections and in critically ill patients is reported in the literature doses up to 9 million IU per. day in divided doses. The clinical data on efficacy and safety of these regimens are very limited and caution is advised.	The suggested dose recommendations for patients with renal impairment is based on the total daily standard dose of 3-6 million IU per. day. In patients with renal impairment, for whom higher doses (eg. Up to 9 million IU per. Day) would be considered if their renal function was normal, corresponding proportional adjustments considered when the dose should be calculated. Caution is advised when Colistimethate Atrium "Xellia" administered to patients with impaired renal function because of the limited information that is available on the safety and appropriate dosage regimens. Creatinine clearance (% of normal value) 76-100 (normal): 3x1,3-2 Mill IU, total daily dose 4-6 mill IU, 40-75 (mild): 2x 1-1,5, total daily dose 2-3 Mill IU 25-40 (moderate): 1-2x 1Mill IU, total daily dose 1-2 Mill IU <25 (severe): 1-1,5 Mill IU every 36 h, total daily dose 0,6-1 Mill IU	see adults	After administration in patients with cystic fibrosis (CF) of 7.5 mg / kg per day. day in divided doses given as intravenous infusions of 30 minutes duration to steady state, Cmax was measured to be 23 (+6) mg / l, while Cmin at 8 hours were 4.5 (+4) mg / l In another study in CF patients who received 2 million units every 8 hour for 12 days, the Cmax was 12.9 mg / l (5.7 to 29.6 mg / l), and Cmin was 2.76 mg / l (1.0 to 6.2 mg / l). In healthy volunteers who received a bolus injection of 150 mg (about 2 million units), mean maximal serum concentrations of 18 mg / l 10 minutes after injection. Protein binding is low. Polymyxins persist in the liver, kidneys, brain, heart and muscles. Colistins volume of distribution following administration of colistimethate sodium in healthy volunteers and in patients with cystic fibrosis has been reported as being respectively 12.4 l and 20.4 l In comparison, colistins volume of distribution following administration of colistimethate sodium proved to be between 90.6 l and 139.9 L in critically ill patients. The increase in the volume of distribution in critically ill patients can lead to a delay in the achievement of effective plasma concentrations. Therefore, the use of an initial loading dose of up to 9 million IU been proposed, especially in the critically ill. In critically ill patients receiving 2 million IU and 3 million IU of colistimethate sodium three times a day intravenously, was observed peak plasma concentrations of colistin, respectively, 2.21 and 2.93 mg / L. Biotransformation: Colistimethate Natriumis converted to polymyxin E1 and polymyxin E2 (colistin) in vivo. It is estimated that approximately 30% of colistimethate sodium is converted to colistin. Elimination: The primary route of elimination of unchanged colistimethate sodium following parenteral administration is renal, with approximately. 60% of a parenteral dose recovered in the urine within 8 hours. Since colistimethate primarily excreted in the urine, a dose reduction is necessary in renal impairment to prevent accumulation. See the table in section. 4.2. The free colistinbase is not excreted through the kidneys	Colistimethate Natrium "Xellia" is indicated for the treatment of the following infections caused by susceptible aerobic gram-negative bacteria: Hospital acquired pneumonia (HAP), Complicated urinary tract infections It is recommended to choose Colistimethate Atrium "Xellia" when antibacterial agents commonly used to treat these infections are not considered to be appropriate for the individual patient and / or the or the underlying pathogen	2013/6

Austria	Tadim® 1 Million I.E. Pulver zur Herstellung einer Infusionslösung	Profile Pharma	Up to 60 kg: 50,000 IU / kg (4 mg / kg) of body weight of up to 75,000 IU / kg (6 mg / kg) over 24 hours. The total daily dose should be administered as three equal doses at 8-hour intervals. Over 60 kg: 1-2 million IU every 8 hour. The standard maximum dose is 6 million IU (480 mg) over 24 hours. Limited pharmacokinetic data from critically ill patients suggest that the use of a loading dose and doses that are higher than standarddoserne may be appropriate. In severe infections and in critically ill patients is reported in the literature doses up to 9 million IU per. day in divided doses. The clinical data on efficacy and safety of these regimens are very limited and caution is advised.	see Xellia	see adults	see Xellia	Tadim is indicated for the treatment of the following infections caused by susceptible aerobic gram-negative bacteria: Hospital acquired pneumonia (HAP), Complicated urinary tract infections It is recommended to choose Tadim when antibacterial agents commonly used to treat these infections are not considered to be appropriate for the individual patient and / or the or the underlying pathogen	2012/4
Belgium	COLISTINEB 2 million U.I. poudre pour solution injectable, solution pour perfusion ou inhalation	Forest UK	Up to 60kg: 50,000 units / kg / day to a maximum of 75,000 units / kg / day. The total daily dose is preferably divided into three doses with an interval of about 8 hours. Above 60 kg: 1-2 million units three times a day. The maximum dose is 6 million units per 24 hours.	Above 60 kg body weight: 20-50 (mild): 3x1-2mill IU, 10-20 (moderate): 1 mill IU every 12-18h, <10 (severe): i mill IU every 18-24h	see adults	An estimate of the serum concentration is recommended, especially in renal failure, newborns and patients with cystic fibrosis. A concentration between 10 and 15 mg / l (about 125-200 units / ml) should normally be suitable for most infections. After administration to patients with cystic fibrosis of 7.5 mg / kg / day divided into doses administered as an IV infusion of 30 minutes until the steady state Cmax was determined to be 23 ± 6 mg / l and Cmin after 8 hours was 4.5 + 4 mg / l. In another study of patients with cystic fibrosis who received 2 million units every 8 hours for 12 days, Cmax was 12.9 mg / l (5.7 to 29.6 mg / l) and Cmin was 2.76 mg / l (1.0 to 6.2 mg / l). In normal volunteers healthy that a bolus injection of 150 mg (approximately 2 million units) was was administered was observed maximum serum concentrations de18 mg / l ten minutes after injection. Protein binding is low. Polymyxins remain in the liver, kidney, brain, heart and muscles. A study of patients with cystic fibrosis reports the volume of distribution at steady state as 0.09 l / kg.	The Colistineb may be considered as intravenous therapy in some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contra-indicated or may be ineffective because of bacterial resistance	2012/12
Bulgaria	Colistin Alvogen colistimethate sodium 1 MIU or 2 MIU	Alvogen IPCo S.à.	Xellia SPC					
Croatia	not available							
Cyprus	Colistin/Norma 1,000,000IU/vial powder for solution for infusion							Jul.13
Czech Republic	COLOMYCIN INJEKCE 1 000 000 mezinárodních jednotek. Prášek pro přípravu injekčního/infuzního roztoku nebo k inhalaci.	Forest UK	The dose is determined by the severity and type of infection and the age, weight and renal function of the patient. If clinical or bacteriological response was slow, dose may be increased according to the patient's condition. To 60 kg of body weight: 50,000 units / kg / day to a maximum of 75,000 units / kg / day. The total daily dose should be divided into three doses given approximately at 8-hour intervals. Above 60 kg body weight: 1-2 million units three times a day. The maximum dose is 6 million units within 24 hours.	Above 60 kg body weight: 20-50 (mild): 3x1-2mill IU, 10-20 (moderate): 1 mill IU every 12-18h, <10 (severe): i mill IU every 18-24h	see adults	Evaluation of serum levels is recommended especially in renal impairment, neonates and patients with cystic fibrosis. Most infections should be sufficient levels of 10-15 mg / l (about 125-200 units / ml) of sodium colistimethate. When administered to patients with cystic fibrosis, 7.5 mg / kg / day in divided doses administered as a 30 minute intravenous infusion Cmax (steady state) was designated 23 ± 6 mg / l and Cmin at 8 hours was 4.5 ± 4 mg / l. In another study with similar patients were given 2 million units every 8 hours for 12 days, the value of Cmax of 12.9 mg / l (5.7 to 29.6 mg / l) and Cmin was 2.76 mg / l (1.0 to 6.2 mg / l). In healthy volunteers who received a bolus injection of 150 mg (approximately 2 million units) , peak serum levels of 18 mg / l observed 10 minutes after injection. Protein binding is low. Polymyxins persist in the liver, kidney, brain, heart and muscles. One study in patients with cystic fibrosis indicates the volume of distribution at steady state of 0.09 l / kg.	Inhalation treatment of pulmonary infections caused by Pseudomonas aeruginosa in patients with cystic fibrosis. Intravenous administration for the treatment of certain serious infections caused by Gram-negative bacteria, including infections of the lower respiratory tract and urinary tract.	2010/7

Denmark	Colistimethatnatrium ”Xellia” Hvert hætteglas indeholder 1 million internationale enheder (IE), hvilket svarer til ca. 80 mg colistimethatnatrium	Xellia/Novo	Up to 60 kg: 50,000 IU / kg (4 mg / kg) of body weight of up to 75,000 IU / kg (6 mg / kg) over 24 hours. The total daily dose should be administered as three equal doses at 8-hour intervals. Over 60 kg: 1-2 million IU every 8 hour. The standard maximum dose is 6 million IU (480 mg) over 24 hours. Limited pharmacokinetic data from critically ill patients suggest that the use of a loading dose and doses that are higher than standarddoserne may be appropriate. In severe infections and in critically ill patients is reported in the literature doses up to 9 million IU per. day in divided doses. The clinical data on efficacy and safety of these regimens are very limited and caution is advised.	The suggested dose recommendations for patients with renal impairment is based on the total daily standard dose of 3-6 million IU per. day. In patients with renal impairment, for whom higher doses (eg. Up to 9 million IU per. Day) would be considered if their renal function was normal, corresponding proportional adjustments considered when the dose should be calculated. Caution is advised when Colistimethate Atrium "Xellia" administered to patients with impaired renal function because of the limited information that is available on the safety and appropriate dosage regimens. Creatinine clearance (% of normal value) 76-100 (normal): 3x1,3-2 Mill IU, total daily dose 4-6 mill IU, 40-75 (mild): 2x 1-1,5, total daily dose 2-3 Mill IU 25-40 (moderate): 1-2x 1Mill IU, total daily dose 1-2 Mill IU <25 (severe): 1-1,5 Mill IU every 36 h, total daily dose 0,6-1 Mill IU	see adults	After administration in patients with cystic fibrosis (CF) of 7.5 mg / kg per day. day in divided doses given as intravenous infusions of 30 minutes duration to steady state, Cmax was measured to be 23 (+6) mg / l, while Cmin at 8 hours were 4.5 (+4) mg / l In another study in CF patients who received 2 million units every 8 hour for 12 days, the Cmax was 12.9 mg / l (5.7 to 29.6 mg / l), and Cmin was 2.76 mg / l (1.0 to 6.2 mg / l). In healthy volunteers who received a bolus injection of 150 mg (about 2 million units), mean maximal serum concentrations of 18 mg / l 10 minutes after injection. Protein binding is low. Polymyxins persist in the liver, kidneys, brain, heart and muscles. Colistins volume of distribution following administration of colistimethate sodium in healthy volunteers and in patients with cystic fibrosis has been reported as being respectively 12.4 l and 20.4 l In comparison, colistins volume of distribution following administration of colistimethate sodium proved to be between 90.6 l and 139.9 L in critically ill patients. The increase in the volume of distribution in critically ill patients can lead to a delay in the achievement of effective plasma concentrations. Therefore, the use of an initial loading dose of up to 9 million IU been proposed, especially in the critically ill. In critically ill patients receiving 2 million IU and 3 million IU of colistimethate sodium three times a day intravenously, was observed peak plasma concentrations of colistin, respectively, 2.21 and 2.93 mg / L. Biotransformation: Colistimethate Natriumis converted to polymyxin E1 and polymyxin E2 (colistin) in vivo. It is estimated that approximately 30% of colistimethate sodium is converted to colistin. Elimination: The primary route of elimination of unchanged colistimethate sodium following parenteral administration is renal, with approximately. 60% of a parenteral dose recovered in the urine within 8 hours. Since colistimethate primarily excreted in the urine, a dose reduction is necessary in renal impairment to prevent accumulation. See the table in section. 4.2. The free colistinbase is not excreted through the kidneys	Colistimethate Atrium "Xellia" is indicated for the treatment of the following infections caused by susceptible aerobic gram-negative bacteria: Hospital acquired pneumonia (HAP), Complicated urinary tract infections It is recommended to choose Colistimethate Atrium "Xellia" when antibacterial agents commonly used to treat these infections are not considered to be appropriate for the individual patient and / or the or the underlying pathogen	2013/5
Denmark	Promixin® (colistimethate sodium)	Swedish Orphan Biovitrum GmbH						
Estonia	not available?	Swedish Orphan Biovitrum GmbH						
European Pharmacopoeia			Colistin is given parenterally, as colistimethate sodium, by intramuscular injection or slow intravenous injection or infusion. In the UK, usual doses are 1 to 2 million units 3 times daily (maximum dose 6 million units in 24 hours) for adults and children weighing more than 60 kg; those weighing up to 60 kg may be given 50 000 units/kg daily in 3 divided doses up to a maximum of 75 000 units/kg daily. In the USA, the usual dose is equivalent to colistin base 2.5 to 5 mg/kg daily in 2 to 4 divided doses. Monitoring of plasma concentrations is required in some patients	In the UK, the following intravenous doses have been suggested for patients weighing more than 60 kg based on creatinine clearance (CC): CC 20 to 50 mL/minute: 1 to 2 million units every 8 hours CC 10 to 20 mL/minute: 1 million units every 12 to 18 hours CC less than 10 mL/minute: 1 million units every 18 to 24 hours US licensed product information also suggests dosage modifications in renal impairment (but defines this in terms of plasma-creatinine concentrations as: mild, 1.3 to 1.5 mg per 100 mL; moderate, 1.6 to 2.5 mg per 100 mL; severe, 2.6 to 4.0 mg per 100 mL). The following intravenous doses (equivalent to colistin base) have been suggested based on the degree of impairment: mild: 2.5 to 3.8 mg/kg daily, given in 2 divided doses moderate: 2.5 mg/kg daily, given as a single dose or in 2 divided doses severe: 1.5 mg/kg daily, given every 36 hours		Plasma-concentration monitoring during systemic treatment is recommended in neonates, patients with renal impairment, and those with cystic fibrosis. Peak plasma-colistin concentrations of 10 to 15 mg/litre (about 125 to 200 units/mL) are recommended. Peak plasma concentrations usually occur 2 to 3 hours after an intramuscular injection of colistimethate sodium. Some colistimethate sodium may be hydrolysed to colistin in vivo. The serum half-life of colistimethate sodium is 2 to 3 hours but is prolonged in renal impairment. It may initially be prolonged in neonates but has been reported to fall to 2 to 3 hours after 3 or 4 days. Colistin is reversibly bound to body tissues, but binding does not occur with colistimethate. Colistimethate is mainly excreted by glomerular filtration as changed and unchanged drug and up to 80% of a parenteral dose may be recovered in the urine within 24 hours. Excretion is more rapid in children than in adults; it is diminished in patients with renal impairment. Colistin crosses the placenta but diffusion into the CSF is negligible. It is distributed into breast milk.	Colistin is a polymyxin antibacterial that has been used in the treatment of severe Gram-negative infections, especially those due to Pseudomonas aeruginosa, although other drugs are usually preferred.	2006/8

Finland	no product found	Promixin® (colistimethate sodium)						
France	COLIMYCINE 1 000 000 UI Poudre et solution pour préparation injectable Boîte de 50 Flacons de poudre de 1 MUI	Sanofi-Aventis	Adults and older children:75000-150000 IU / kg / day, administered in 1-3 doses, max. 12 IU/day;	CrCl>30ml/min: normal dosing regimen. CrCl 10-30 ml/min: 30000- 50 000 IU / kg every 12-18h. CrCl <10 ml/min: 30000- 50 000 IU / kg every18-24h.	Infants: from 150,000 to 225,000 IU / kg / day administered in 1 to 3 injections, max 12 MIU/ day.		microbiologically documented infections caused by sensitive Gram-negative bacteria. It is recommended to use this antibiotic in combination to avoid emergence of resistance kidney, . urogenital, . sepsis, . meningeal (including coverage in local treatment). - In exceptional cases dermatology: . leg ulcers: current license limited to ulceration superinfection; tissue infection around the ulcer requiring systemic antibiotics; . superinfectionof superficial burns and superficial wounds.	2013/2
Germany	Colistimethat-Natrium Infectopharm 1 Mio.I.E. Pulver zur Herstellung einer Injektions- oder Infusionslösung	Infectopharm mu	Up to 60 kg: 50,000 IU / kg (4 mg / kg) of body weight of up to 75,000 IU / kg (6 mg / kg) over 24 hours. The total daily dose should be administered as three equal doses at 8-hour intervals. Over 60 kg: 1-2 million IU every 8 hour. The standard maximum dose is 6 million IU (480 mg) over 24 hours. Limited pharmacokinetic data from critically ill patients suggest that the use of a loading dose and doses that are higher than standard dose may be appropriate. In severe infections and in critically ill patients is reported in the literature doses up to 9 million IU per. day in divided doses. The clinical data on efficacy and safety of these regimens are very limited and caution is advised.	The suggested dose recommendations for patients with renal impairment is based on the total daily standard dose of 3-6 million IU per. day. In patients with renal impairment, for whom higher doses (eg. Up to 9 million IU per. Day) would be considered if their renal function was normal, corresponding proportional adjustments considered when the dose should be calculated. Caution is advised when Colistimethate Atrium Infectopharm administered to patients with impaired renal function because of the limited information that is available on the safety and appropriate dosage regimens. Creatinine clearance (% of normal value) 76-100 (normal): 3x1,3-2 Mill IU, total daily dose 4-6 mill IU, 40-75 (mild): 2x 1-1,5, total daily dose 2-3 Mill IU 25-40 (moderate): 1-2x 1Mill IU, total daily dose 1-2 Mill IU <25 (severe): 1-1,5 Mill IU every 36 h, total daily dose 0,6-1 Mill IU	see adults	After administration in patients with cystic fibrosis (CF) of 7.5 mg / kg per day. day in divided doses given as intravenous infusions of 30 minutes duration to steady state, Cmax was measured to be 23 (+6) mg / l, while Cmin at 8 hours were 4.5 (+4) mg / l In another study in CF patients who received 2 million units every 8 hour for 12 days, the Cmax was 12.9 mg / l (5.7 to 29.6 mg / l), and Cmin was 2.76 mg / l (1.0 to 6.2 mg / l). In healthy volunteers who received a bolus injection of 150 mg (about 2 million units), mean maximal serum concentrations of 18 mg / l 10 minutes after injection. Protein binding is low. Polymyxins persist in the liver, kidneys, brain, heart and muscles. Colistins volume of distribution following administration of colistimethate sodium in healthy volunteers and in patients with cystic fibrosis has been reported as being respectively 12.4 l and 20.4 l In comparison, colistins volume of distribution following administration of colistimethate sodium proved to be between 90.6 l and 139.9 L in critically ill patients. The increase in the volume of distribution in critically ill patients can lead to a delay in the achievement of effective plasma concentrations. Therefore, the use of an initial loading dose of up to 9 million IU been proposed, especially in the critically ill. In critically ill patients receiving 2 million IU and 3 million IU of colistimethate sodium three times a day intravenously, was observed peak plasma concentrations of colistin, respectively, 2.21 and 2.93 mg / L. Biotransformation: Colistimethate Natrium partly converts in vivo to colistin base More PK info is available in the SPC	Colistimethate sodium Infectopharm is indicated for the treatment of the following infections caused by susceptible aerobic gram-negative bacteria - Nosocomial Pneumonia - Complicated urinary tract infections	2013/8
Germany	Promixin 1 MIO I.E.Pulver zur Herst einer Inf.Lsg	Swedish Orphan Biovitrum GmbH (Profile Pharma)						

Greece	COLISTIN / NORMA Powder for solution for infusion. Each vial contains 75 mg Colistin Messilate Sodium, equivalent to 1.000.000 IU.	Norma	Adults (including the elderly): The usual total daily dose is between 6,000,000 and 9,000,000 units. Cystic fibrosis require higher doses recommended in order to maintain therapeutic drug levels in blood serum. In severe infections, in critically ill patients, it is recommended total daily dose of 9,000,000 units. Pharmacokinetic data in critically ill patients advocate a loading dose . For all patients, regardless of the renal function, the initial loading dose (with an upper limit of 9,000,000 units) can be calculated by the following formula: Loading dose = desired concentration of colistin in plasma at steady state x bodyweight x 60.000 The next dose (first dose maintenance therapy) should be administered 24 hours after the loading dose, The desired concentration of colistin in plasma at steady state depends on the MIC of the organism (whichcould be higher), the location and severity of infection. As the value of body weight use lower values corresponding to the ideal or actual weight. For example, a patient with severe infection, 67Kg body weight and a bacterial strain with MIC = 1mg/liter and desired concentration of colistin in plasma at steady state = 2 mg / liter, the loading dose is about 8,000,000 units.	When the creatinine clearance is <70 ml/min/1, 73m^2 the required total daily dose (after loading dose), expressed in mill IU colistimethate sodium (with an upper limit of 9,000,000 units) can be estimated by applying the following formula: Total daily dose = desired concentration of colistin in plasma at steady state x (1,5 x creatinine clearance + 30) x 30.000 In this formula creatinine clearance is expressed in ml/min/1, 73m2. For example, in a patient with severe infection strain with MIC =1mg/liter colistin and desired plasma concentration at steady state = 2 mg / liter, having a creatinine clearance = 40 ml/min/1, 73m2, the total daily dose is 5.4 million units. In patients with creatinine clearance <10 ml/min/1, 73m2, the interval between doses should be 12 hours. In patients with creatinine clearance> 10 ml/min/1, 73m2, the interval between doses may be 12 or 8 hours. In patients on hemodialysis, the day not on dialysis, the total daily dosage is 900,000 units for each desired 1mg/liter colistin plasma concentration at steady state. Therefore, like in the previous example, if the patient was on dialysis the total daily dose, the day not on dialysis, would be 1,800,000 units, administered in two doses of 900,000 units every 12 hours). On the day of dialysis if the dose administered at the end of the session, the dose must be 30% higher dose given it is not the day on dialysis (approximately 1,200,000 units, in the example above). If the dose is administered during the last hour of the session the dose must be 50% higher given it is not the dayon dialysis (1,350,000 units, in the example above). In patients on continuous renal replacement (CRRT: CVVHD and CVVH) the dosage is approximately 5,700,000 units (administered in two or three divided doses) for any desired concentration of colistin 1mg/liter in plasma at steady state. Especially in this patient group the recommended dose reaches usually similar concentrations compared to patients with normal renal function.	50,000 units / kg / day with a maximum dose of 75,000 units / kg / day. The total daily dose should be divided into three doses administered in intervals of eight hours.	Extensive PK section available	Colistin / Norma ® is indicated for the treatment severe infections caused by Gram (-) bacteria (when sensitivity tests indicate that they are caused by susceptible strains), including those of the lower respiratory and urinary system when the most widely used systematic antibacterial agents are contraindicated or ineffective because of resistance of bacteria to these.	
Hungary	Colomycin 2 000 000 NE por oldatos injekcióhoz, infúzióhoz vagy inhalációs oldathoz. 2 000 000 NE kolisztimetát-nátrium injekciós üvegenként	Forest Laboratories UK	Children and adults (including the elderly): Body weight ≤ 60 kg: 50 000 IU / kg / day, up to 75 000 IU / kg / day. The total daily dose is divided into three parts, which is to be administered at intervals of about 8 hours. ☐ 60 kg body weight: 1-2 million IU three times a day. The maximum dose of 6 million units in 24 hours.	Creatinine clearance (ml/min), Over 60kg bodyweight: 20-50 (mild): 3x1-2mill IU, 10-20 (moderate): 1 mill IU every 12-18h, <10 (severe): 1 mill IU every 18-24h	see adults	If the clinical or bacteriological inadequate the dose may be increased so, as required by the patient. Determination of serum levels of renal impairment is particularly recommended for infants and cystic fibrosis. In patients with fibrosis. Most infections of 10 - 15 mg / l sodium colistimethate level (about 125-200 IU / mL) is considered appropriate. PK see Germany	Inhalation therapy: pulmonary infections caused by Pseudomonas aeruginosa in cystic fibrosis (CF). Intravenous therapy: Serious gram-negative bacterial infections, including lower respiratory tract and urinary tract infections, and where the use of conventional systemic antibiotics is contraindicated or is ineffective because of bacterial resistance.	2009/10
Ireland	Colomycin Injection 1 million or 2 million International Units. Powder for solution for injection, infusion or inhalation.	Forest Laboratories UK	Up to 60 Kg: 50,000 IU-75,000 IU/Kg dailys. The total daily dose should be administered as three equal doses at 8 hourly intervals. Over 60 Kg: 1-2 million IU every 8 hours. The maximum standard dose is 6 million IU (480 mg) in 24 hours. Anomalous distribution in patients with cystic fibrosis may require higher doses in order to maintain therapeutic serum levels.	Creatinine clearance (ml/min), Over 60kg bodyweight: 20-50 (mild): 3x1-2mill IU, 10-20 (moderate): 1 mill IU every 12-18h, <10(severe): i mill IU every 18-24h	see adults	More PK info is available in the SPC	Intravenous administration for the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contra-indicated or may be ineffective because of bacterial resistance.	
Italy	Colimicina Im Fl 1000000u4ml+f - Ucb Pharma Spa	UCB Pharma Spa	Over 60 Kg: 1-2 million IU every 8 hours. The maximum standard dose is 6 million IU (480 mg) in 24 hours.	Loading dose of 25.000 IU/kg, the maintenance dosage may be adjusted by reducing the dose, while maintaining a fixed interval of 12 hours or prolonging the dosage interval and maintaining the fixed dose of 25.000 IU/kg.	see adults	Protein binding is low. Polymyxins persist in the liver, kidneys, br	Acute or chronic infections due to susceptible strains of the following gram-negative bacteria: Enterobacter aerogenes, Escherichia coli, Klebsiella pneumoniae and, in particular, Pseudomonas aeruginosa. This antibiotic is not indicated for infections caused by Proteus and Neisseria.	

Latvia	not available?	Swedish Orphan Biovitrum GmbH	Anomalous distribution in patients with cystic fibrosis may require higher doses in order to maintain therapeutic serum levels.	10-20 (moderate): 1 mill IU every 12-18h,				
Lithuania	not available?	Swedish Orphan Biovitrum GmbH		<10 (severe): 1 mill IU every 18-24h				
Luxemburg								
Malta	COLOMYCIN INJECTION 1 million or 2 million International Units. Powder for solution for injection, infusion or inhalation. Each vial contains either 1 million or 2 million International Units Colistimethate Sodium.	Forest Laboratories UK	Should clinical or bacteriological response be slow the dose may be increased as indicated by the patient's condition. Up to 60kg: 50,000 units/kg/day to a maximum of 75,000 units/kg/day. The total daily dose should be divided into three doses given at approximately 8-hour intervals. Over 60kg: 1-2 million units three times a day. The maximum dose is 6 million units in 24 hours.	Creatinine clearance (ml/min), Over 60kg bodyweight: 20-50 (mild): 3x1-2mill IU, 10-20 (moderate): 1 mill IU every 12-18h, <10 (severe): 1 mill IU every 18-24h	See adults	Serum level estimations are recommended especially in renal impairment, neonates and cystic fibrosis patients. Levels of 10–15 mg/l (approximately 125-200 units/ml) colistimethate sodium should be adequate for most infections. PK see Germany	Intravenous administration for the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contra-indicated or may be ineffective because of bacterial resistance.	2012/11
Poland	COLISTIN TZF 500 000 j.m.; 1 000 000 j.m. Proszek do sporządzania roztworu do wstrzykiwań, infuzji i inhalacji (Colistimethatum natricum) 500 000 j.m. (około 40 mg) kolistymetatu sodowego 1 000 000 j.m. (około 80 mg) kolistymetatu sodowego	Polfa Tarchomin S.A.	Patients with a body weight of 60 kg: 50 000 IU / kg. (4 mg / kg) to a maximum of 75 000 IU / kg. (6 mg / kg) daily in three divided doses (every 8 hours). Patients weighing more than 60 kg: 1 000 000 to 2 000 000 IU three times a day (every 8 hours). The maximum daily dose is 6 000 000 IU	Dosing regimen in patients weighing more than 60 kg. Creatinine clearance [Ml / min] 20-50: 1 to 2 million IU every 8 hours Creatinine clearance [Ml / min] 10-20: 1 million IU every 12 to 18 hours Creatinine clearance [Ml / min] <10: 1 million IU every 18 to 24 hours The exact amount of dosage should be determined on the basis of the antibiotic concentration in the blood and toxicity symptoms.	info only for inhaled form	It is recommended to measure serum concentrations of colistin, especially in renal impairment, in neonates. Serum CMS concentrations of 125-200 IU / ml (10 to 15 ug / ml) are adequate to treat most infections.	Severe systemic infections caused by susceptible strains of Gram-negative bacteria (for example, sepsis, infections of the urinary tract), when routinely used antibiotics are contraindicated or not effective.	2009/10
Portugal	Colistina Generis 1000000 UI Pó para solução injectável ou para solução para inalação por nebulização Colistimetato de sódio	Generis Farmacêu	60 kg of body weight: 50,000 units / kg / day to 75,000 units / kg / day. The daily total dose should be divided into three doses administered at intervals of approximately 8 hours. More than 60 kg body weight: 2.1 MIU three times a day. The maximum dose is 6 MUI in 24 hours.	Dosage for patients with more than 60 kg: Creatinine Clearance (Ml / min) 20-72: 1-2 MIU every 8 hours Creatinine Clearance (Ml / min) 10-20: 1 MIU every 12-18 hours Creatinine Clearance (Ml / min) <10: 1 MIU every 18-24 hours	The following recommended doses serve only as a guideline and should be adjusted According to clinical response: Children <2 years 500000-1 MIU twice a day. Children> 2 years and adults: 1 - 2 MIU twice a day	If the clinical and bacteriological response is low, the dose may be increased according with the condition of the patient. The determination of serum levels is recommended, especially in patients with renal failure, newborns and cystic fibrosis. Levels of 10-15 mg / l (About 125-200 units / ml) of sodium colistimethate be suitable for most infections	Generis colistin may be used to treat respiratory infections in persons with cystic fibrosis when they are caused by Pseudomonas aeruginosa. Colistin Generis is usually administered in these patientsby inhalation. Colistin generis is sometimes administered as a solution through a vein to treat serious infections caused by certain types of bacteria. These infections some include pneumonia and some infections of the kidneys. Colistin Generis is not commonly used to treat these types of infections, but can be used if other antibiotics, which are usually used for these infections are not suitable for any reason, for example, if the person is infected is allergic to other antibiotics or bacteria are resistant to many of these other antibiotics.	2012/11

Romania	COLISTINĂ ANTIBIOTICE 1.000. COLISTINĂ ANTIBIOTICE 1.000. COLISTINĂ ANTIBIOTICE 1.000. COLISTINĂ ANTIBIOTICE 1.00.000 UI, pulbere pentru soluţie injectabilă/perfuzabilă	S.C. ANTIBIOTICE	The usual dose is 50.000 IU of colistin / kg body weight. The dose depends on the severity and type of infection, age, weight and degree of impairment of kidney function. If the clinical or bacteriological response is not adequate, the dosage may be increased depending on the condition of the patient. Up to 60 kg body weight: 50,000 IU / kg body weight up to a maximum of 75,000 IU / kg body weight per day. The total daily dose should be divided into 3 equal doses administered every 8 hours. More than 60 kg: 1-2 million IU three times a day at intervals of 8 hours. The maximum dose is 6 million IU per day.	In moderate and severe renal impairment, the excretion of colistimethate sodium is delayed. Accordingly, doses and dose ranges will be adjusted to prevent the accumulation of the drug. Patients with ≥60kg body weight: Creatinine Clearance (Ml / min) 20-50: 1-2 MIU every 8 hours Creatinine Clearance (Ml / min) 10-20: 1 MIU every 12-18 hours Creatinine Clearance (Ml / min) <10: 1 MIU every 18-24 hours		It is recommended to measure serum concentrations of colistin, especially in renal impairment, in neonates. Serum concentrations of 125-200 IU / ml are adequate to treat most infections. In healthy volunteers, after 10 min of injection 150 mg colistin bolus (approximately 2 million units) the maximum concentration was 18 mg / l. The plasma protein binding is low. Polymyxin persists in liver, kidney, brain, heart and muscles and does not achieve therapeutic concentrations in the cerebrospinal fluid and brain. The main route of elimination is renal excretion. 80% of the administered dose is recovered unchanged in the urine. Since there is no excretion into the bile it can be considered that the remaining drug is inactivated in the tissues. The mechanism is unknown.	Severe infections caused by Gram-negative, including lower respiratory tract and urinary tract, if other antibiotics for systemic use are contraindicated or resistant	2012/12
Slovakia	Colimycine plv ino 1 MIU (v 1 liekovke) 1x50 lag	sanofi-aventis Slo	an average of 50-100 000 IU / kg / day, i.e. usually 3 million IU daily in 2-3 divided doses intramuscularly or 1-hour intravenous infusion.	Serum creatinine level <15 mg / l, creatinine clearance> 80 ml / min: 50000 IU /kg / day with a maximum dose 150000 IU /kg/day. Serum creatinine level of 15-35 mg / l, creatinine clearance 30-80 ml / min: 30000 IU /kg/day and the maximum dose of 60000 IU /kg/day. Serum creatinine level 35-100 mg / l, creatinine clearance 5-30 ml / min: 15000 IU / kg / day and the maximum dose of 30 000 IU / kg / day. Serum creatinine level> 100 mg / L, creatinine clearance <5 ml / min: 1 million. IU every 2-3 days and a maximum dose of 30 000 IU / kg, further to 1 million IU twice a week. Anuria at a dose of 1 million IU after each hemodialysis, a maximum dose of 30 thousand. IU / kg and continuing with up to 1 million IU after each hemodialysis	In children, neonates and premature infants at a dose of 50 to 100 thousand / kg / day according to the severity of the infection. Total daily dose is divided into 2-3 single doses to be administered intramuscularly or by slow intravenous infusion (1 h).	After parenteral administration, 80 mg (1 million IU) kolimycínu result in peak plasma concentrations (about 3.3 ug / ml) and are reached within 1-2 hours after application. Half-life is approximately 2-3 hours. Kolimycín does not cross the blood-brain barrier under normal conditions and does not pass into the ocular, synovial and pleural fluid. Does not cross the placental barrier. In breast milk kolimycín is excreted only in very small quantities, which do not have a clinical effect on the infant. Kolimycínu binding to plasma proteins is approximately 15%. Kolimycín is not biotransformed and 70-80% of the administered dose was excreted in urine within 24 hours. Urinary concentration 2 hours after administration gives approximately 24 ug / ml, and 8 hours after the 10 ug / ml.	Urogenital infections, ENT and respiratory infections, intraabdominal infections, biliary tract infections, septicemia, meningitis	2007/2
Slowakia	KOLOMYCÍN INJEKCIA 1 milión IU	Forest UK						Jän.10
Slovenia								

Spain	COLISTIMETATO DE SODIO GES Polvo 1 MUI/vial The active substance is sodium colistimethate. Each vial contains 1 million international units (MIU) equivalent to approximately 80 mg of colistimethate sodium	Alfa Wassermann S.p.A.	Up tp 60 kg: 50,000 IU / kg body weight per day. Total daily dose should be given as three equal doses at 8 hour intervals. More than 60 kg body weight: 1 to 2 MIU every 8 hours (three times a day) without exceeding a maximum daily dose of 6 MIU. Dosing instructions for inhalation avialable	Additional adjustments may be required according to the individual needs of each patient. Creatinine 1,2-1,46 mg/100 ml: creatinine clearance (40-75% of normal): 1-1,5 Mill IU/12 h up to a maximal daily dose of 2-3 Mill IU Creatinine 1,47-2,42 mg/100 ml: creatinine clearance (25-40% of normal): 0,8-2 Mill IU/12-24 h up to a maximal daily dose of 1,5-2 Mill IU Creatinine 2,43-3,85 mg/100 ml: creatinine clearance (<25% of normal):1-1,5 Mill IU/36 h up to a maximal daily dose of 0,6-1 Mill IU	dosing recommendations only for inhalation	Sodium colistimethate has a low plasma protein binding. Polymyxins are known to persist in muscle tissue, liver, kidney, heart and brain. In a study in which patients with cystic fibrosis received 5-7 mg / kg / day divided into 3 doses that were administered by intravenous infusion over 30 minutes Cmax was 21,4 ± 5 mg / l and Cmin was 2.8 ± 1.8 mg / l. The Cmax at steady state was 23 ± 6mg/l and Cmin was 4.5 ± 4 mg / l. In another study in patients with cystic fibrosis who received 2 MIU every 8 hours for 12 days, Cmax was 12.9 mg / l (5.7 to 29.6 mg / l) and Cmin was 2.76 mg / l (1.0 to 6.2 mg / l). Intravenous administration of 150 mg (about 2 MUI) to healthy volunteers produced serum levels of 18 mg / l at 10 minutes. The volume of distribution obtained in a study in patients with cystic fibrosis was 0.09 l / kg. In vivo sodium colistimethate is converted to its base. Approximately 80% of the dose is recovered in urine unchanged. There is no biliary excretion. After intravenous administration, excretion is primarily renal with recovery of 40% of the parenteral dose in the urine within 8 hours and about 80% at 24 hours. Following intravenous administration to healthy adults, the half-life is approximately 1.5 hours, in contrast to a half-life of 3.4 ± 1.4 hours in patients with cystic fibrosis who were administered a single intravenous infusion over 30 minutes.	Sodium colistimethate G.E.S. is an antibiotic used to treat serious infections in the respiratory and urinary tract if they are caused by microorganisms susceptible to colistimethate sodium. It also can be used to treat certain infections in patients with cystic fibrosis.	2004/7
Spain	Colixin 1MUI. Polvo para solución inyectable o para solución para inhalación por nebulizador	Pharmis Biofrmaceutica						Mär.11
Spain	Colistimetato de sodio G.E.S. 1 MUI polvo pa ra solución inyectable/para inhalación por nebulizador	G.E.S; Genéricos Españoles Laboratorio						Aug.04
Spain		Profile						Jun.05

Sweden	Tadim, 1 miljon internationella enheter (IE), pulver till infusionsvätska, lösning 1 injektionsflaska innehåller 1 miljon internationella enheter (IE), vilket motsvarar ca 80 mg kolistimetatnatrium	Profile Pharma, (Nigaard Pharma AS/Norge filial)	Up to 60 kg: 50,000 IU / kg (4 mg / kg) of body weight of up to 75,000 IU / kg (6 mg / kg) over 24 hours. The total daily dose should be administered as three equal doses at 8-hour intervals. Over 60 kg: 1-2 million IU every 8 hour. The standard maximum dose is 6 million IU (480 mg) over 24 hours. Limited pharmacokinetic data from critically ill patients suggest that the use of a loading dose and doses that are higher than standard dose may be appropriate. In severe infections and in critically ill patients is reported in the literature doses up to 9 million IU per. day in divided doses. The clinical data on efficacy and safety of these regimens are very limited and caution is advised.	The suggested dose recommendations for patients with renal impairment is based on the total daily standard dose of 3-6 million IU per. day. In patients with renal impairment, for whom higher doses (eg. Up to 9 million IU per. Day) would be considered if their renal function was normal, corresponding proportional adjustments considered when the dose should be calculated. Caution is advised when Tadim is administered to patients with impaired renal function because of the limited information that is available on the safety and appropriate dosage regimens. Creatinine clearance (% of normal value) 76-100 (normal): 3x1,3-2 Mill IU, total daily dose 4-6 mill IU, 40-75 (mild): 2x 1-1,5, total daily dose 2-3 Mill IU 25-40 (moderate): 1-2x 1Mill IU, total daily dose 1-2 Mill IU <25 (severe): 1-1,5 Mill IU every 36 h, total daily dose 0,6-1 Mill IU	See adults	Distribution The volume of distribution of colistin following administration of colistimethate sodium in healthy volunteers and in patients with cystic fibrosis has been reported to be 12.4 l and 20.4 l In comparison, the volume of distribution for colistin following administration of colistimethate sodium is found to be between 90.6 and 139 l , 9 l in critically ill patients. The increased volume of distribution in critically ill patients may lead to a delay in achieving effective plasma concentrations. Therefore, using an initial loading dose of up to 9 million IU proposed, particularly in critically ill patients. Of critically ill patients receiving colistimethate 2 million IU and 3 million IU intravenously three times per day was observed peak plasma concentrations of 2.21 and 2.93 mg / L. Biotransformation Colistimethate converted in vivo to polymyxin E1 and polymyxin E 2 (colistin). It has been estimated that about 30% of colistimethate sodium is converted to colistin. Elimination Colistimethate is primarily excreted unchanged in the urine where hydrolysis to the active portion continues. Following intravenous administration is 62% of the dose in the urine within 8 hours. Colistin is not excreted by the kidneys. Half-life of colistin following administration of colistimethate sodium in healthy volunteers and in patients with cystic fibrosis has been reported to be 3 hours and 4.2 hours. Half-life of colistin following administration of colistimethate sodium has been reported to increase when administered to critically ill patients compared with healthy volunteers, and the mean half-life is estimated to vary from about 5.9 hours to 7.4 hours after intravenous administration in critically ill patients. In patients with impaired renal function decreases elimination of colistimethate sodium and a higher percentage can be converted to colistin, leading to increased colistin concentrationer in plasma.	Tadim is indicated for the treatment of the following infections caused by susceptible aerobic gram-negative bacteria - Nosocomial Pneumonia - Complicated urinary tract infections	2011/12

The Netherlands	Tadim, 1 miljoen internationale eenheden (IE) poeder voor oplossing voor infusie. Elke injectieflacon bevat 1 miljoen internationale eenheden (IE) wat overeenkomt met ongeveer 80 mg colistimethaatnatrium	Profile Pharma	Up to 60 kg: 50,000 IU / kg (4 mg / kg) of body weight of up to 75,000 IU / kg (6 mg / kg) over 24 hours. The total daily dose should be administered as three equal doses at 8-hour intervals. Over 60 kg: 1-2 million IU every 8 hour. The standard maximum dose is 6 million IU (480 mg) over 24 hours. Limited pharmacokinetic data from critically ill patients suggest that the use of a loading dose and doses that are higher than standard dose may be appropriate. In severe infections and in critically ill patients is reported in the literature doses up to 9 million IU per. day in divided doses. The clinical data on efficacy and safety of these regimens are very limited and caution is advised.	The suggested dose recommendations for patients with renal impairment is based on the total daily standard dose of 3-6 million IU per. day. In patients with renal impairment, for whom higher doses (eg. Up to 9 million IU per. Day) would be considered if their renal function was normal, corresponding proportional adjustments considered when the dose should be calculated. Caution is advised when Tadim is administered to patients with impaired renal function because of the limited information that is available on the safety and appropriate dosage regimens. Creatinine clearance (% of normal value) 76-100 (normal): 3x1,3-2 Mill IU, total daily dose 4-6 mill IU, 40-75 (mild): 2x 1-1,5, total daily dose 2-3 Mill IU 25-40 (moderate): 1-2x 1Mill IU, total daily dose 1-2 Mill IU <25 (severe): 1-1,5 Mill IU every 36 h, total daily dose 0,6-1 Mill IU	See adults	Distribution The volume of distribution of colistin following administration of colistimethate sodium in healthy volunteers and in patients with cystic fibrosis has been reported to be 12.4 l and 20.4 l In comparison, the volume of distribution for colistin following administration of colistimethate sodium is found to be between 90.6 and 139 l , 9 l in critically ill patients. The increased volume of distribution in critically ill patients may lead to a delay in achieving effective plasma concentrations. Therefore, using an initial loading dose of up to 9 million IU proposed, particularly in critically ill patients. Of critically ill patients receiving colistimethate 2 million IU and 3 million IU intravenously three times per day was observed peak plasma concentrations of 2.21 and 2.93 mg / L. Biotransformation Colistimethate converted in vivo to polymyxin E1 and polymyxin E 2 (colistin). It has been estimated that about 30% of colistimethate sodium is converted to colistin. Elimination Colistimethate is primarily excreted unchanged in the urine where hydrolysis to the active portion continues. Following intravenous administration is 62% of the dose in the urine within 8 hours. Colistin is not excreted by the kidneys. Half-life of colistin following administration of colistimethate sodium in healthy volunteers and in patients with cystic fibrosis has been reported to be 3 hours and 4.2 hours. Half-life of colistin following administration of colistimethate sodium has been reported to increase when administered to critically ill patients compared with healthy volunteers, and the mean half-life is estimated to vary from about 5.9 hours to 7.4 hours after intravenous administration in critically ill patients. In patients with impaired renal function decreases elimination of colistimethate sodium and a higher percentage can be converted to colistin, leading to increased colistin concentrationer in plasma.	Tadim is indicated for the treatment of the following infections caused by susceptible aerobic gram-negative bacteria - Nosocomial Pneumonia - Complicated urinary tract infections	2011/11
The Netherlands	COLISTINEB 2 miljoen I.E. poeder voor oplossing voor injectie, infusie of inhalatie. Elke injectieflacon bevat 2 miljoen Internationale Eenheden natriumcolistimethaat	Forest UK	Up to 60 Kg: 50,000 IU-75,000 IU/Kg dailys. The total daily dose should be administered as three equal doses at 8 hourly intervals. Over 60 Kg: 1-2 million IU every 8 hours. The maximum standard dose is 6 million IU (480 mg) in 24 hours. Anomalous distribution in patients with cystic fibrosis may require higher doses in order to maintain therapeutic serum levels.	Creatinine clearance (ml/min), Over 60kg bodyweight: 20-50 (mild): 3x1-2mill IU, 10-20 (moderate): 1 mill IU every 12-18h, <10 (severe): 1 mill IU every 18-24h	see adults	see UK Forest	Intravenous administration for the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contra-indicated or may be ineffective because of bacterial resistance.	Dez.12
UK	Promixin, 1 million International Units (IU), Powder for Solution for Infusion	IU, mg/kg (dosing)	Up to 60 Kg: 50,000 IU/Kg (4 mg/Kg) to a maximum of 75,000 IU/Kg (6 mg/Kg), in 24 hours. The total daily dose should be administered as three equal doses at 8 hourly intervals. Over 60 Kg: 1-2 million IU every 8 hours. The maximum standard dose is 6 million IU (480 mg) in 24 hours.	Creatinine Clearance (% of normal): 76-100 (normal): 3x 1.3 to 2 mill IU (4-6 total daily dose), 40 - 75 (mild): 2x 1-1.5 (2-6 total daily dose), 25-40 (moderate): 1-2x 1 mill IU (1-2 total daily dose), <25 (severe): 1-1.5 every 36 hours (0.6-1 total daily dose)	see adults	Limited pharmacokinetic data from critically ill patients suggest that use of a loading dose and higher than standard doses may be appropriate. For severe infections and in critically ill patients doses up to 9 million IU per day in divided doses, have been reported in the literature. Clinical efficacy and safety data with these regimens are very limited and caution is advised.	infections caused by susceptible aerobic Gram-negative bacteria: Hospital acquired pneumonia (HAP), complicated urinary tract infections	2011/9

UK	Colistimethate Sodium 1 Million I.U. Powder for Solution for Injection	Beacon Pharmace	Up to 60 Kg: 50,000 IU-75,000 IU/Kg dailys. The total daily dose should be administered as three equal doses at 8 hourly intervals. Over 60 Kg: 1-2 million IU every 8 hours. The maximum standard dose is 6 million IU (480 mg) in 24 hours. Estimation of serum levels is particularly recommended for patients with renal impairment, neonates and patients with cystic fibrosis. Serum levels of 10 - 15 mg/l (approximately 125-200 units/ml) should be adequate for most infections.	Creatinine clearance (ml/min), Over 60kg bodyweight: 20-50 (mild): 3x1-2mill IU, 10-20 (moderate): 1 mill IU every 12-18h, <10(severe): i mill IU every 18-24h	see adults	PK info only in CF	Intravenous administration for the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contra-indicated or may be ineffective because of bacterial resistance	2011/3
UK	Colomycin Injection 1 million or 2 million International Units. Powder for solution for injection, infusion or inhalation.	Forest Laboratories UK	Up to 60 Kg: 50,000 IU-75,000 IU/Kg dailys. The total daily dose should be administered as three equal doses at 8 hourly intervals. Over 60 Kg: 1-2 million IU every 8 hours. The maximum standard dose is 6 million IU (480 mg) in 24 hours. Anomalous distribution in patients with cystic fibrosis may require higher doses in order to maintain therapeutic serum levels.	Creatinine clearance (ml/min), Over 60kg bodyweight: 20-50 (mild): 3x1-2mill IU, 10-20 (moderate): 1 mill IU every 12-18h, <10 (severe): 1 mill IU every 18-24h	see adults	Serum level estimations are recommended especially in renal impairment, neonates and cystic fibrosis patients. Levels of 10–15 mg/l (approximately 125-200 units/ml) colistimethate sodium should be adequate for most infections.	Intravenous administration for the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contra-indicated or may be ineffective because of bacterial resistance.	2012/8
UK	Promixin, 1 million International Units (IU), Powder for Solution for Infusion	Profile Pharma	Up to 60 Kg: 50,000 IU/Kg (4 mg/Kg) to a maximum of 75,000 IU/Kg (6 mg/Kg), in 24 hours. The total daily dose should be administered as three equal doses at 8 hourly intervals. Over 60 Kg: 1-2 million IU every 8 hours. The maximum standard dose is 6 million IU (480 mg) in 24 hours. Limited pharmacokinetic data from critically ill patients suggest that use of a loading dose and higher than standard doses may be appropriate. For severe infections and in critically ill patients doses up to 9 million IU per day in divided doses, have been reported in the literature. Clinical efficacy and safety data with these regimens are very limited and caution is advised.	Creatinine Clearance (% of normal): 76-100 (normal): 3x 1.3 to 2 mill IU (4-6 total daily dose), 40 - 75 (mild): 2x 1-1.5 (2-6 total daily dose), 25-40 (moderate): 1-2x 1 mill IU (1-2 total daily dose), <25 (severe): 1-1.5 every 36 hours (0.6-1 total daily dose)	see adults	In critically ill patients given colistimethate sodium 2 million IU and 3 million IU three times a day intravenously, peak colistin plasma concentrations of 2.21 and 2.93 mg/L, respectively, were observed.	Hospital acquired pneumonia (HAP, Complicated urinary tract infections	2011/11