

Harmonisation of SPCs in the European Union (Article 30)

Active Substance	Indication adults	Dosage adults with normal kidney function	Notes	EC Decision
Amoxicillin/clavulanic acid 250 mg/125 mg	<p>Treatment of the following infections in adults and children.</p> <ul style="list-style-type: none"> • Acute bacterial sinusitis (adequately diagnosed) • Cystitis • Pyelonephritis • Cellulitis • Animal bites • Severe dental abscess with spreading cellulitis. 	Adults and children ≥ 40 kg 250 mg/125 mg three times a day.	Indications applicable for the low dose form	19 Oct 2009
Ceftazidim	<ul style="list-style-type: none"> • Nosocomial pneumonia • Broncho-pulmonary infections in cystic fibrosis> • Bacterial meningitis • Chronic suppurative otitis media • Malignant otitis externa • Complicated urinary tract infections • Complicated skin and soft tissue infections • Complicated intra-abdominal infections • Bone and joint infections • Peritonitis associated with dialysis in patients on CAPD. 	1-2 g every 8 h or 12 h Loading dose of 2 g followed by a continuous infusion of 4 to 6 g every 24 h (max 9g/day)		13 Jan 2011
Ceftriaxone				Ongoing
Cefuroxime	<ul style="list-style-type: none"> • Acute streptococcal tonsillitis and pharyngitis. • Acute bacterial sinusitis. • Acute otitis media. • Acute exacerbations of chronic bronchitis. • Cystitis. • Pyelonephritis. • Uncomplicated skin and soft tissue infections. • Treatment of early Lyme disease. 	250-500 mg twice daily		23 Aug 2012
cefuroxime	<ul style="list-style-type: none"> • Community acquired pneumonia. • Acute exacerbations of chronic bronchitis. • Complicated urinary tract infections, including pyelonephritis. • Soft-tissue infections: cellulitis, erysipelas and wound infections. • Intra-abdominal infections • Prophylaxis against infection in gastrointestinal (including oesophageal), orthopaedic, cardiovascular, and gynaecological surgery (including caesarean 	750-1500mg every 8 hours. Surgical prophylaxis for gastrointestinal, gynaecological surgery (including caesarean section) and orthopaedic operations 1.5g with the induction of anaesthesia. This may be supplemented with two 750 mg doses (intramuscularly) after 8 hours and 16 hours. Surgical prophylaxis for cardiovascular and oesophageal operations 1.5g with induction of anaesthesia followed by 750 mg (intramuscularly)	Restrictions and deletion of indications. Revising of duration of dosing in prophylaxis	10 Sept 2012

	section).	every 8 hours for a further 24 hours.		
Meropenem	<ul style="list-style-type: none"> • Pneumonia, • Bronchopulmonary infections in cystic fibrosis, • Complicated urinary tract infections, • Intra-abdominal infections, Intra- and post-partum infections • Complicated skin and soft tissue infections • Acute bacterial meningitis 	<p>Dose three times daily:</p> <ul style="list-style-type: none"> • Pneumonia (CAP, HAP), cUTI, cIAI, intra-post-partum inf., cSSTI: 500mg-1g • Broncho-pulmonary infections in cystic fibrosis, meningitis: 2g • Febrile neutropenic pat.: 1g <p>Up to 2 g three times daily, especially in nosocomial infections due to P. aeruginosa or Acinetobacter spp</p>	i.v. over approximately 15 to 30 minute. Extended infusion or continuous infusion is not mentioned	15 Oct 2009
Imipenem/cilastatin	<ul style="list-style-type: none"> • Complicated intra-abdominal infections • Severe pneumonia including hospital and ventilator-associated pneumonia • Intra- and post-partum infections • Complicated urinary tract infections • Complicated skin and soft-tissue infections • May be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection. • Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. 	<ul style="list-style-type: none"> • 500 mg/500 mg every 6 hours OR 1000 mg/1000 mg every 8 hours OR every 6 hours • It is recommended that infections suspected or proven to be due to less susceptible bacterial species (such as Pseudomonas aeruginosa) and very severe infections (e.g. in neutropenic patients with a fever) should be treated with 1000 mg/1000 mg administered every 6 hours. 	Revising of wording, restricting and deleting of indications. Revising of dosing recommendations	
Piperacillin/tazobactam	<ul style="list-style-type: none"> • Severe pneumonia including hospital-acquired and ventilator-associated pneumonia • Complicated urinary tract infections (including pyelonephritis) • Complicated intra-abdominal infections • Complicated skin and soft tissue infections (including diabetic foot infections) • Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. • May be used in the management of neutropenic patients with fever suspected to be due to a bacterial infection. 	<p>The usual dose is 4 g piperacillin / 0.5 g tazobactam given every 8 hours.</p> <p>For nosocomial pneumonia, sepsis, and bacterial infections in neutropenic patients, the recommended dose is 4 g piperacillin / 0.5 g tazobactam administered every 6 hours.</p>	administered by intravenous infusion (over 30 minutes). Extended infusion or continuous infusion is not mentioned	21 Feb 2011
Ciprofloxacin (excluding modified release tablet)	<ul style="list-style-type: none"> • Lower respiratory tract infections due to Gram-negative bacteria <ul style="list-style-type: none"> ○ Exacerbations of chronic obstructive pulmonary disease ○ Broncho-pulmonary infections in cystic fibrosis or in bronchiectasis ○ Pneumonia • Chronic suppurative otitis media 	<ul style="list-style-type: none"> • 500-750 mg twice daily: Lower respiratory tract infections, complicated pyelonephritis, prostatitis, Epididymo-orchitis and pelvic inflammatory diseases, Intra-abdominal infections due to Gram-negative bacteria, SSTI, Bone and joint infection, treatment of infections or prophylaxis of infections in neutropenic patients 	Indications acute sinusitis, septicaemia due to Gram negative bacteria, selective digestive decontamination in immunosuppressed patients have been withdrawn and the indication Infections of the	07 Oct 2008

	<ul style="list-style-type: none"> • Acute exacerbation of chronic sinusitis especially if these are caused by Gram-negative bacteria • Urinary tract infections • Gonococcal urethritis and cervicitis • Epididymo-orchitis including cases due to Neisseria gonorrhoeae • Pelvic inflammatory disease including cases due to Neisseria gonorrhoeae • Infections of the gastro-intestinal tract (e.g. travellers' diarrhoea) • Intra-abdominal infections • Infections of the skin and soft tissue caused by Gram-negative bacteria 	<ul style="list-style-type: none"> • 250-500 mg twice daily: uncomplicated cystitis • 500 mg twice daily: Complicated cystitis, uncomplicated pyelonephritis, diarrhoea, inhalation anthrax post-exposure prophylaxis and curative treatment • 500mg single dose: gonococcal urethritis and cervicitis , Prophylaxis of invasive infections due to Neisseria meningitidis 	lower respiratory tract has been restricted	
Levofloxacin	<ul style="list-style-type: none"> • Indicated only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of these infections. <ul style="list-style-type: none"> ○ Acute bacterial sinusitis ○ Acute exacerbations of chronic bronchitis ○ Community-acquired pneumonia ○ Complicated skin and soft tissue infections • Pyelonephritis and complicated urinary tract infections • Chronic bacterial prostatitis • Uncomplicated cystitis • Inhalation Anthrax: postexposure prophylaxis and curative treatment <p>Levofloxacin Tablets may also be used to complete a course of therapy in patients who have shown improvement during initial treatment with intravenous levofloxacin.</p>	500 mg once daily all indications except CAP and cSSTI (500mg twice daily)	Restrictions in RTI, updated warnings	31 July 2012
Teicoplanin	<ul style="list-style-type: none"> • Complicated skin and soft tissue infections, • Bone and joint infections, • Hospital acquired pneumonia, • Community acquired pneumonia, • Complicated urinary tract infections, • Infective endocarditis, • Peritonitis associated with continuous ambulatory peritoneal dialysis (CAPD), • Bacteraemia that occurs in association with any of the indications listed above. • Alternative oral treatment for Clostridium difficile infection associated diarrhoea and colitis. 	Link	Harmonisation of the active substance specification	12 Sept 2013