

**Prescribing Protocol SESLHDPR/655
Ceftolozane/tazobactam**

Title	Ceftolozane/tazobactam Prescribing Protocol
Areas where Protocol/ Guideline applicable	District Inpatient ward areas including intensive care
Areas where Protocol/ Guideline not applicable	Outpatient Paediatrics
Authorised Prescribers	Infectious Diseases physician or Microbiologist
Indication for use	Indicated for the treatment of the following infections in adults suspected or proven to be caused by designated susceptible pathogen which are resistant to all other available agents like penicillin and enzyme inhibitor combination (piperacillin/tazobactam), carbapenem (meropenem) and fluoroquinolone (ciprofloxacin): <ul style="list-style-type: none"> - Complicated intra-abdominal infections in combination with metronidazole - Complicated urinary tract infections, including pyelonephritis Infection caused by isolates producing ESBL and OXA-48 carbapenemase but NOT AmpC, KPC and MBL producing organisms.
Clinical condition	Indicated for the treatment of infections in adults suspected or proven to be caused by designated susceptible microorganisms which are resistant to all other available agents like penicillin and enzyme inhibitor combination (piperacillin/tazobactam), carbapenem (meropenem) and fluoroquinolone (ciprofloxacin)
Contra-indications	Known hypersensitivity to ceftolozane/tazobactam, or members of the cephalosporin class, or other members of the beta-lactam class.
Precautions	Ceftolozane/tazobactam is eliminated by the kidneys. Dosage adjustment is required with creatinine clearance <50mL/min Sodium restriction – each vial contains 230mg (10mmol) sodium
Place in Therapy	Directed therapy based on positive microbiology. Second or third line depending on clinical picture, MIC, patient tolerability and resistance mechanism. GuidanceMS “Red” antibiotic requiring prior ID/Micro approval for initiation; only to be stocked in Pharmacy. It will be used for multi-drug resistant Pseudomonas and other organism such as isolates producing ESBL and OXA-48 carbapenemase which are susceptible to ceftolozane-tazobactam
Dosage (Include dosage adjustment for specific patient groups)	1 vial (1000mg/500mg) every 8 hours via intravenous infusion Ceftolozane/tazobactam is eliminated primarily by the kidneys <ul style="list-style-type: none"> - Dosage adjustments CrCl< 50mL/min required
Duration of therapy	Complicated intra-abdominal infection: up to 14 days or as approved by Infectious Disease Complicated urinary tract infections, including pyelonephritis: seven days or as approved by Infectious Disease
Important Drug Interactions	Nil

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Administration instructions	Infuse intravenously over 60 minutes Reconstitute with either water for injection or 0.9% sodium chloride, add to 100mL of compatible fluid <u>Storage:</u> 2°C - 8°C. Refrigerate. Do not freeze.
Monitoring requirements	Resolution of clinical signs and symptoms; improvement in laboratory parameters; clearance of blood cultures; serum creatinine levels.
Management of complications	Consideration of discontinuation of therapy and management of the specific complication, if severe
Basis of Protocol/Guideline (including sources of evidence, references)	Product Information TGA available online for ceftolozane-tazobactam (Zerbaxa) attached accessed 13/8/2018 Cluck D et al, Ceftolozane-tazobactam: A new generation cephalosporin, AJHSP 2015 Product information (MIMS online) for meropenem 08/03/2016. Accessed 13/08/2018 Product information (MIMS online) for ciprofloxacin 28/02/2012. Accessed 13/08/2018 Australian Medicines Handbook (online), Ceftolozane/tazobactam monograph. Accessed 14/08/2019 Australian Injectable Drugs Handbook, 7th Edition (online), Ceftolozane/tazobactam monograph. Accessed 14/08/2019
Groups consulted in development of this protocol	DIDISH, AMS CAAG (SESLHD/ISLHD)
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GOVERNANCE	
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Chairperson, QUM Committee	Prof George Rubin
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