

Guidance Sheet 5b: IMP administration



Centre for
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Drug Name	AZTEC IMP for I.V. infusion	For AZTEC clinical trial use only																									
Dosage	Doses 1-3 inclusive: 10ml/kg once daily Doses 4-10 inclusive: 5ml/kg once daily																										
Preparation	<p align="center">**Use aseptic technique, as per local guidelines**</p> <p>Each AZTEC IMP treatment pack contains 12 vials (1 for each of 10 days treatment, plus 2 spare). Each vial is enclosed in a cardboard blinding carton.</p> <p align="center">**The vials must not be removed from the blinding carton**</p> <ol style="list-style-type: none"> 1) Check the Pack ID on the treatment pack label matches the Pack ID assigned to the baby (see printout from randomisation system and daily log) 2) Select one AZTEC IMP vial from the treatment pack (all are identical). Check vial ID also matches assigned number. 3) Add 4.8ml of sterile water for injection to an AZTEC IMP vial using a 5ml syringe 4) Discard the 5ml syringe. 5) Gently invert the vial 5 times. 6) Allow vial to stand for a <u>minimum</u> of 5 minutes. <p align="center">**Reconstituted vial gives 100mg in 1ml solution- <u>must be diluted prior to administration</u>- follow dilution steps 7-10**</p> <ol style="list-style-type: none"> 7) Using a 50ml syringe, draw up 49ml of suitable diluent <ul style="list-style-type: none"> o 0.9% saline o 5% dextrose o 0.45% saline o 5% dextrose in 0.45% saline o 5% dextrose in 0.3% saline 8) Using a 2ml/2.5ml syringe, take 1ml (100mg) from the AZTEC IMP vial, and add to the 50ml syringe containing the diluent (this gives the correct IMP administration concentration of 2mg/ml). 9) Discard the used AZTEC IMP vial in its entirety (including the blinding carton), and 2ml/2.5ml syringe, as per local guidelines. 10) Label the syringe containing IMP as per local practise, including the baby's AZTEC study ID e.g. <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Drug added</th> <th>Amount</th> <th>Time</th> <th>Initials</th> </tr> </thead> <tbody> <tr> <td><i>0.9% sodium chloride</i></td> <td><i>49ml</i></td> <td><i>10:00</i></td> <td><i>HCL</i></td> </tr> <tr> <td><i>AZTEC IMP</i></td> <td><i>1ml</i></td> <td><i>10:00</i></td> <td><i>HCL</i></td> </tr> <tr> <td><i>Total</i></td> <td><i>50ml</i></td> <td></td> <td></td> </tr> <tr> <td colspan="4"><i>Patients name: Joseph Bloggs, AZTEC study ID AZ1101</i></td> </tr> <tr> <td colspan="4"><i>Date: 13/05/2019</i></td> </tr> </tbody> </table>			Drug added	Amount	Time	Initials	<i>0.9% sodium chloride</i>	<i>49ml</i>	<i>10:00</i>	<i>HCL</i>	<i>AZTEC IMP</i>	<i>1ml</i>	<i>10:00</i>	<i>HCL</i>	<i>Total</i>	<i>50ml</i>			<i>Patients name: Joseph Bloggs, AZTEC study ID AZ1101</i>				<i>Date: 13/05/2019</i>			
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Administration	<ul style="list-style-type: none"> ▪ Adjust the infusion pump to deliver the required volume over at least 60 minutes. <p>Example: Infusion volume= weight in kg x fluid volume needed (10ml or 5ml)</p> <p>For doses 1-3 for a 500g baby: 0.5 x 10ml = 5 ml 5ml/hour for 60 minutes</p> <p>On doses 4-10 for a 500g baby: 0.5 x 5ml = 2.5ml 2.5ml/hour for 60 minutes</p> <ul style="list-style-type: none"> ▪ Administer intravenously <ul style="list-style-type: none"> ○ Umbilical venous catheter ○ Peripherally inserted central catheter (long line) ○ Peripheral cannula ▪ If access is 'lost' during infusion, continue any residual dose once new access is established, even if some appears to have 'tissued'. Do not repeat the dose with a new vial. Once prepared for infusion the solution is stable for a maximum of 24 hours at room temperature.
Diluents	<ul style="list-style-type: none"> ○ 0.9% saline ○ 5% dextrose ○ 0.45% saline ○ 5% dextrose in 0.45% saline ○ 5% dextrose in 0.3% saline
Compatibilities	Total Parenteral Nutrition (TPN), Adrenaline, Dopamine, Dobutamine, Vancomycin. See full list in AZTEC document box.
Incompatibilities	Amikacin, amiodarone, aztreonam, cefotaxime, ceftazidime, ceftriaxone, chlorpromazine, ciprofloxacin, clindamycin, fentanyl, furosemide (frusemide), gentamicin, imipenem-cilastatin, ketorolac, midazolam, morphine sulphate, mycophenolate mofetil, pentamidine, piperacillin-tazobactam (EDTA-free), potassium chloride, thiopental sodium, ticarcillin-clavulanate, tobramycin.
Monitoring	During Infusion- heart rate and blood pressure IV site for signs of phlebitis Liver function
Side effects	Common: Nausea, vomiting, abdominal pain and diarrhoea (all less than erythromycin). Rare: Increased liver enzymes, hepatitis, hepatic necrosis, hypersensitivity reactions, hypertrophic pyloric stenosis, thrombophlebitis, ventricular dysrhythmias (In general, the risk of dysrhythmias is increased when these agents are administered in combination with other drugs that prolong the QT interval)