Flucloxacillin
Newborn Use Only

Alert
The Antimicrobial Stewardship Team has listed this drug under the following category: Unrestricted.

Indication
Treatment of sepsis where infection by S. Aureus or susceptible coagulase-negative Staphylococci (CoNS) is suspected or confirmed, and other infections caused by susceptible organisms.

Action
Bactericidal agent that works by inhibiting the biosynthesis of cell wall mucopolypeptides. Flucloxacillin is stable against beta-lactamase producing bacteria.

Drug Type
Penicillin antibiotic.

Trade Name
Flucil, Flucloxacillin sodium monohydrate for injection (DBL), Flubiclox

Presentation
500 mg vial, 1000 mg vial, 125 mg/5 mL suspension.

Dosage/Interval
IV, IM or IO: 50 mg/kg/dose. Dosing interval as below.

Oral: 25–50 mg/kg/dose. Dosing interval as below.

Dosing interval for all routes

<table>
<thead>
<tr>
<th>Day of life</th>
<th>Dosing interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days 0–7</td>
<td>12 hourly</td>
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<tr>
<td>Days 8–28</td>
<td>8 hourly</td>
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<tr>
<td>Day 29 +</td>
<td>6 hourly</td>
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</table>

Route
IV
IM (only if IV route not possible as intramuscular route is painful)
IO
Oral

Maximum Daily Dose
200 mg/kg/day

Preparation/Dilution
IV/IO:
Add 4.6 mL of WFI to 500 mg powder for reconstitution (100 mg/mL) OR
Add 9.3 mL of WFI to the 1000 mg powder for reconstitution (100 mg/mL).
Draw up 2.5 mL (250 mg) and add 2.5 mL sodium chloride 0.9% to make a final volume of 5 mL with a concentration of 50 mg/mL.

IM:
Add 1.6 mL of WFI, lidocaine (lignocaine) 0.5% or lidocaine (lignocaine) 1% to 500mg powder for reconstitution (250 mg/mL) OR
Add 3.3 mL of WFI, lidocaine (lignocaine) 0.5% or lidocaine (lignocaine) 1% to the 1000 mg powder for reconstitution (250 mg/mL).

NOTE: DO NOT ADMINISTER LIDOCAINE (LIGNOCAINE) CONTAINING SOLUTIONS INTRAVENOUSLY

Administration
IV: Slow injection over 3–5 minutes.

IM: Inject slowly into a large muscle (if administering a volume greater than 1mL, divide the dose and administer at 2 different injection sites to minimise pain).

Oral: Give 30 to 60 minutes before feeds. Shake the bottle well before measuring dose. Usually reconstituted by Pharmacy. If supplied unreconstituted, reconstitute powder for oral suspension using water for injection with the volume specified on the bottle.

Monitoring
Monitor liver function tests if using high dose/long course or in existing hepatic impairment. Monitor renal function as the drug is mainly renally excreted.

Contraindications
History of flucloxacillin associated jaundice or hepatic dysfunction.
History of a hypersensitivity reaction to beta-lactam antibiotics e.g., penicillins.

Precautions
Use with caution in renal or hepatic impairment.
Use with caution in jaundiced or preterm infants as flucloxacillin can displace bilirubin from albumin.

IM injection can cause pain and irritation – obtaining IV access as soon as possible is
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<table>
<thead>
<tr>
<th>Drug Interactions</th>
<th>Aminoglycosides, including gentamicin, should not be mixed with flucloxacillin when both drugs are given parenterally as inactivation occurs. Ensure line is adequately flushed between antibiotics.</th>
</tr>
</thead>
</table>
| Adverse Reactions | Transient diarrhoea – common with oral doses.  
Hypersensitivity (rare) – urticaria, fever, bronchospasm, anaphylaxis, eosinophilia.  
Phlebitis (much rarer than with dicloxacillin) – monitor injection site.  
Hepatitis and cholestatic jaundice (may occur up to several weeks after stopping), isolated cases of nephritis. |
| Compatibility | Fluids: Glucose 5%, sodium chloride 0.9%.  
Y-site: Adrenaline (epinephrine), aminophylline, ampicillin, dexamethasone sodium phosphate, digoxin, heparin, hydrocortisone sodium succinate, potassium chloride, ranitidine, sodium bicarbonate. |
| Incompatibility | Fluids: Amino acid solutions and lipid emulsions.  
Y-site: Aminoglycosides (e.g., gentamicin), atropine sulfate monohydrate, benzylpenicillin, calcium gluconate monohydrate, ciprofloxacin, dobutamine, erythromycin lactobionate, midazolam, morphine sulfate pentahydrate, vancomycin. |
| Stability | Use immediately following reconstitution.  
Vial is for single use only.  
Reconstituted oral suspension should be discarded after 14 days. |
| Storage | Vial: Store below 25°C.  
Oral suspension: Store powder below 25°C, once reconstituted store solution at 2–8°C. |
| Special Comments | IM administration will result in delayed peak serum concentrations compared with administration via Intravenous or intrasosseous route. |
| Evidence summary | Traditional IV dose regimens for flucloxacillin are based on a pharmacokinetic study from 1987 on 9 infants. The more recent pharmacokinetic study from 2006 suggests that traditional doses are inadequate for *S. aureus* and proposes a regimen of 25 mg/kg/dose 4 hourly for *S. aureus* infections and 10 mg/kg/dose 6 hourly for CoNS (based on Monte Carlo simulation from data obtained from 55 neonates, gestation 26 to 42 weeks), but these regimens have not been prospectively verified in a follow up study 4-8 (Level IV).  
Lidocaine (lignocaine) is used as diluent for IM preparation to reduce the pain at injection site.10,11 |
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<table>
<thead>
<tr>
<th>Original version Date: 05/12/2015</th>
<th>Author: Neonatal Medicines Formulary Consensus Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Version number: 4</td>
<td>Version Date: 31/10/2016</td>
</tr>
<tr>
<td>Risk Rating: High</td>
<td>Due for Review: 31/10/2018</td>
</tr>
<tr>
<td>Approval by: As per Local policy</td>
<td>Approval Date: February 2016</td>
</tr>
</tbody>
</table>

This RHW document is a modification of Neomed version. Dosage schedules remain the same. However, information on the commercial preparations not used at RHW might have been deleted. The risk rating might have been modified as per the local health district policy.