### Flucloxacillin Monograph - Paediatric

**Scope (Staff):** Medical, Nursing, Pharmacy  
**Scope (Area):** PCH

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**DESCRIPTION**
- Flucloxacillin is a bactericidal penicillin antibiotic with narrow spectrum of activity specific to Gram positive organisms, excluding methicillin resistant staphylococcus aureus (MRSA).
- It interferes with the bacterial cell wall peptidoglycan synthesis resulting in cell lysis.¹
- Flucloxacillin is indicated for the treatment of confirmed or suspected methicillin susceptible Staphylococcal infections (e.g. bacteraemia, osteomyelitis, pneumonia, cellulitis).²

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**INDICATIONS AND RESTRICTIONS**

**IV and Oral: Unrestricted (green) antibiotic**
This is not a restricted agent. Follow standard ChAMP guidelines where appropriate.

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**FORMULATIONS**

**Available at PCH:**
- 250mg/5mL oral liquid (Flucil®)
- 250mg and 500mg capsules (Staphlex®)
- 500mg and 1g powder for injection vial (Flucil®)

**Other formulations available:**
- 125mg/5mL and 250mg/5mL oral liquid – multiple generic brands
- 250mg and 500mg capsules (Flopen®)
- 500mg and 1g powder for injection vial (DBL brand, Flubiclox®)

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**DOSAGE**
- The doses listed below fall within the standard range. Higher doses may be prescribed for certain situations in consultation with Infectious Diseases or Clinical Microbiology consultants.

**IV:**
- Usual dose: 25mg/kg/dose (to a maximum of 1 gram) 6 hourly³, ⁴
- Severe infections (including osteomyelitis): 50mg/kg/dose (to a maximum of 2 grams) 4 to 6 hourly.³, ⁴ Four hourly dosing should be used in critically unwell patients, those with CNS infections and/or endocarditis.
- **Surgical Prophylaxis:** 50mg/kg/dose (to a maximum of 2 grams) as a single dose 15 to 30 minutes before knife to skin.³

**Oral:**
- Usual dose: 12.5mg/kg/dose (to a maximum of 500mg) 6-hourly.³, ⁴
- Severe infections (including osteomyelitis): 25mg/kg/dose (to a maximum of 1 gram) 6-hourly.³, ⁴
- Although 6 hourly dosing is preferred, giving the four doses evenly spaced throughout the waking hours has been used in children.⁵

**Neonates:**
- Please refer to neonatal clinical care drug protocols

### DOSAGE ADJUSTMENT

- Dosage adjustment required in renal impairment:
- Dosage adjustment may be required in cases of impaired renal function (with creatinine clearance of less than 10mL/min).⁴, ⁵
- To calculate the estimated glomerular filtration rate (eGFR) use the following formula (also available via the link)⁵

\[
eGFR (\text{mL/min/1.73m}^2) = \frac{36.5 \times \text{height (cm)}}{\text{Serum creatinine (micromol/L)}}
\]

- CrCl ≥10mL/minute: normal dose
- CrCl <10mL/minute: 100% dose 8-hourly.⁴

**Dosage adjustment in hepatic impairment:**
- There is no dosage adjustment required in hepatic impairment.
- However, flucloxacillin is contraindicated in patients with a history of jaundice or hepatic dysfunction associated with dicloxacillin or flucloxacillin.¹

### RECONSTITUTION

**IV:**
- Reconstitute each vial with the volume of water for injection in the table below. Further dilution with a compatible fluid to a concentration of 50mg/mL is required prior to administration.¹, ², ⁶, ⁷

<table>
<thead>
<tr>
<th>Vial strength</th>
<th>Volume of water required</th>
<th>Resulting concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>500mg</td>
<td>4.6mL</td>
<td>100mg/mL</td>
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<tr>
<td>1 gram</td>
<td>9.2mL</td>
<td>100mg/mL</td>
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**Oral (Flucil® 250mg/5mL strength):**
- Open foil packaging and reconstitute with 58mL of water as follows: tap bottle until all powder flows freely; add approximately half the total volume of water for reconstitution and shake vigorously to
suspend powder. Add remainder of the water and again shake vigorously. Store reconstituted solution in the refrigerator (between 2 and 8ºC) and discard any remaining suspension after 14 days.\(^2\)
- Refer to packaging for the reconstitution instructions for alternative brands and strengths.

**ADMINISTRATION**

**IV bolus:**
- Administer a 50mg/mL or weaker solution over 3 to 5 minutes.
- Doses greater than 25mg/kg are best given via IV infusion to reduce the risk of phlebitis.
- Rapid administration of large doses has also been associated with seizures.\(^1,6\)

**IV infusion:**
- Dilute to a suitable volume with diluent and infuse over 20 to 30 minutes.
- Doses greater than 25mg/kg are best infused to avoid phlebitis.\(^1,6\)

**Continuous infusion:**
- May be given over 24 hours by continuous infusion. Contact Pharmacy for advice.\(^6\)

**Oral:**
- Give on an empty stomach at least 30 minutes before food or 2 hours after food.\(^1,5\)

**MONITORING**
- Renal, hepatic and haematological function should be monitored weekly with prolonged therapy (i.e. longer than 7 days).\(^1\) Hepatic adverse effects are more likely with larger doses or long treatment courses (greater than 2 weeks).\(^1\)

**ADVERSE EFFECTS**
- **Common:** transient increases in liver enzymes and bilirubin, diarrhoea, nausea, pain and inflammation at injection site, allergy.\(^1,4\)
- **Rare:** cholestatic hepatitis, vomiting, *Clostridium difficile*-associated disease, electrolyte disturbances, neurotoxicity (usually with high doses, e.g. drowsiness, hallucinations, coma, seizures), bleeding, blood dyscrasias (e.g. neutropenia, which is related to dose and duration of treatment, thrombocytopenia).\(^1,4\)

**COMPATIBLE FLUIDS**
- Glucose 5%
- Glucose/sodium chloride solutions
- Sodium chloride 0.9%
- Hartmann’s.\(^6\)

**STORAGE**
- 250mg and 500mg capsules – store below 25 ºC and protect from light
- 500mg and 1g powder for injection vial – store below 25 ºC and
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<table>
<thead>
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<tbody>
<tr>
<td>• 250mg/5mL oral liquid – store unreconstituted bottle below 25 °C and protect from light.</td>
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<tr>
<td>• After reconstitution, store in the refrigerator (between 2 and 8 °C) and discard any remaining solution after 14 days.</td>
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<tr>
<th>PRECAUTIONS</th>
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<tr>
<td>• Use with extreme caution in jaundiced neonates or premature infants as it reduces albumin bound bilirubin to 50 – 70% of the baseline concentration.</td>
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<tr>
<th>CONTRAINDICATIONS</th>
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<tr>
<td>• Flucloxacillin is contraindicated in patients with a history of flucloxacillin or dicloxacillin associated jaundice or hepatic dysfunction.1, 2, 4</td>
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<tr>
<td>• Flucloxacillin is contraindicated in patients with history of severe allergy to penicillins.</td>
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<tr>
<td>• Care should also be taken with cephalosporins and carbapenems as cross reactivity may occur between penicillins, cephalosporins and carbapenems.1, 2, 4</td>
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<th>INTERACTIONS</th>
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<tr>
<td>Flucloxacillin has few drug interactions; please consult PCH approved references (such as Clinical Pharmacology), your ward pharmacist or Pharmacy on 6456 0190 (option 1) for more information</td>
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<td>• IV aminoglycoside antibiotics are inactivated by IV penicillins and cephalosporins. Aminoglycoside antibiotics are rapidly bactericidal and should be administered first. The line should then be flushed well with a compatible fluid and the penicillin administered.1, 6</td>
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<tr>
<td>• Probenecid inhibits excretion of penicillins which may increase flucloxacillin levels and increase the risk of seizures in certain patients1</td>
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<tr>
<td>• Each 1 gram of flucloxacillin contains 2mmol of sodium.6</td>
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<tr>
<th>MANUFACTURER SAFETY DATA SHEET (SDS)</th>
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<tr>
<td>To access the Manufacturer SDS for this product, use the following link to ChemAlert.</td>
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**Please note: The information contained in this guideline is to assist with the preparation and administration of flucloxacillin. Any variations to the doses recommended should be clarified with the prescriber prior to administration**
Related internal policies, procedures and guidelines

Antimicrobial Stewardship Policy (Medication Management Manual)
ChAMP Empiric Guidelines

References