**Amoxicillin (Amoxycillin)/Clavulanic Acid Monograph - Paediatric**

| Scope (Staff): | Clinical Staff – Medical, Nursing, Pharmacy |
| Scope (Area): | PCH |

This document should be read in conjunction with this [DISCLAIMER](#)

### DESCRIPTION

- Amoxicillin is a penicillin antibiotic which interferes with cell wall synthesis by binding to penicillin-binding proteins resulting in cell lysis.\(^1\)\(^-\)\(^4\)
- Clavulanic acid is a beta-lactamase inhibitor, it extends the spectrum of activity of amoxicillin against many beta-lactamase producing organisms such as some strains of *Staphylococcus aureus* and *Haemophilus influenzae*.\(^1\)

### INDICATIONS AND RESTRICTIONS

**Oral: Unrestricted (Green) antibiotic**

- This is not a restricted agent. Follow standard ChAMP guidelines where appropriate.

### CONTRAINDICATIONS

- Immediate hypersensitivity to amoxicillin, clavulanic acid, other beta-lactam antibacterial drugs (eg, penicillins, cephalosporins), or any component of the formulation.\(^2\)
- Care should also be taken when using amoxicillin/clavulanic acid in those with a history of immediate-type reaction to a cephalosporin or carbapenem as cross-reactivity may occur.\(^1,\)\(^2\)
- History of cholestatic jaundice or hepatic dysfunction with amoxicillin/clavulanate potassium therapy.\(^2\)

### PRECAUTIONS

- Amoxicillin with clavulanic acid is associated with a higher incidence of rash when used in patients with infectious mononucleosis, acute lymphoblastic leukaemia, chronic lymphocytic leukaemia and HIV infection.\(^1\)

### FORMULATIONS

Available at PCH:

**Tablet:**
- Duo Forte® - 875mg amoxicillin with 125mg clavulanic acid.

**Suspension:**
- Duo 400® - 400mg amoxicillin with 57mg clavulanic acid per
5mL oral powder for suspension.

**NOT stocked at PCH (non-formulary):**

**Tablet:**
- Duo® - 500mg amoxicillin with 125mg clavulanic acid tablets

**Suspension:**
- Suspension® - 125mg amoxicillin with 31.25mg clavulanic acid per 5mL oral powder for suspension.

**Intravenous:**
- There is no intravenous formulation available in Western Australia hospitals.

### DOSAGE

- The doses listed below fall within the standard range. Higher doses may be prescribed for certain situations in consultation with an infectious diseases or clinical microbiology consultant.

- All doses are expressed and should be prescribed as the amoxicillin component (doses refer to the Duo 400® and Duo Forte® preparations).

**Oral:**
- (Products with amoxicillin component of 400mg/5mL or 875mg per tablet).
- **Usual dose:** 25mg/kg/dose (to a maximum of 875mg) twice daily.

- **Severe infections (including for acute bacterial sinusitis):** 35mg/kg/dose (to a maximum of 875mg) twice daily.

**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 30mL/min) due to the increased risk of crystalluria.

- For patients with a creatinine clearance of less than 30mL/minute, the higher strength preparations (i.e. the 875mg/125mg tablets and 400mg/57mg per 5mL suspension) should be avoided due to the clavulanic acid component and the risk of crystalluria.

- The lower strength preparations (i.e. 500mg/125mg and 125mg/31.25mg per 5 mL suspension) may be suitable.

- Contact Pharmacy for further information.

**Dosage adjustment required in hepatic impairment:**
- Amoxicillin with clavulanic acid is contraindicated in patients with a history of cholestatic jaundice or hepatic dysfunction.
associated with its use. Care should be taken when using amoxicillin with clavulanic acid in patients with hepatic impairment due to other causes, although no specific dose reductions are recommended.1,3,6

**RECONSTITUTION**

**Oral suspension (Curam Duo® 400mg/57mg per 5mL – Sandoz brand):**
- Reconstitute the Sandoz brand amoxicillin with clavulanic acid with 55mL of water for reconstitution as follows: Tap the bottle until all the powder flows freely.
- Add approximately half the amount of water for reconstitution and shake vigorously to suspend the powder.
- Add the remainder of the water and again shake vigorously. Store the reconstituted suspension between 2 and 8 degrees and discard any remaining suspension after 7 days.8
- Refer to packaging for the reconstitution instructions for alternative brands and strengths.

**ADMINISTRATION**
- Amoxicillin with clavulanic acid preparations should be taken immediately before food or with the first mouthful of food to minimise gastrointestinal intolerance and to optimise absorption.1,2,7,8
- The suspension should be shaken well prior to measuring out the dose.2,7

**MONITORING**
- Renal, hepatic and haematological function should be monitored weekly with prolonged therapy (i.e. longer than 14 days).1,2,8

**ADVERSE EFFECTS**
- **Common:** diarrhoea, nausea, transient increases in liver enzymes and bilirubin, rash1
- **Rare:** pustular drug eruption, cholestatic hepatitis (mainly due to clavulanic acid and is usually reversible), vomiting, *Clostridium difficile*-associated diarrhoea, black tongue, neurotoxicity, bleeding, blood dyscrasias (e.g. neutropenia, thrombocytopenia), immunologic reactions (include rash, erythema, urticaria, contact dermatitis, fever, anaphylactic shock, angioedema, bronchospasm, interstitial nephritis, haemolytic anaemia, eosinophilia, serum sickness-like syndrome, exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis.)1

**COMPATIBLE FLUIDS**
- Not applicable

**STORAGE**
- Store below 25°C. Protect from moisture and light.
INTERACTIONS

- Probenecid decreases penicillin excretion by competitive renal tubule secretion, prolonging its activity; may allow use of oral rather than IV route by maintaining adequate penicillin concentration.
- Allopurinol when co-administered with amoxicillin: increases risk of rash occurring; be aware of the possibility.

MANUFACTURER SAFETY DATA SHEET (SDS)

- To access the Manufacturer SDS for this product, use the following link to ChemAlert.

**Please note: The information contained in this guideline is to assist with the preparation and administration of amoxicillin/clavulanic acid. 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 (ChAMP Manual)

References

7. MIMS Australia Pty Ltd. MIMS [online]. St Leonards (NSW): CMPMedica Australia Pty Ltd; accessed online 9th May 2017.

Useful resources (including related forms)

- Neonatology Clinical Care Unit Medication Protocols (KEMH)
### Amoxicillin Clavulanic Acid Monograph - Paediatric

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