MONOGRAPH

Clarithromycin Monograph - Paediatric

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

QUICKLINKS

Dosage/Dosage Adjustments | Administration | Compatibility | Monitoring

DRUG CLASS

Macrolide antibiotic.[1-3]

INDICATIONS AND RESTRICTIONS

- Clarithromycin is used in the treatment of *Bordetella pertussis;* in combination therapy for the prevention and treatment of *Mycobacterium avium* complex (MAC) and other non-tuberculosis mycobacterium infections; and for *Helicobacter pylori* eradication.[2, 3]

Oral: Unrestricted (green) antibiotic

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

CONTRAINDICATIONS

- Hypersensitivity to clarithromycin, macrolide antibiotics or any component of the formulation.[2, 4-6]
- Clarithromycin is contraindicated in concurrent treatment with cisapride, colchicine, domperidone, ergometrine, oral midazolam, simvastatin or ticagrelor.[2, 5, 7]
- History of cholestatic jaundice or hepatic dysfunction with prior use of clarithromycin.[5]

PRECAUTIONS

- Clarithromycin has multiple clinically significant drug interactions, consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.[2, 4, 6]
- Clarithromycin may prolong the QT interval increasing the risk of arrhythmias, this risk is further increased in patients with electrolyte disturbance.[2-5, 7, 8]
- Clarithromycin should be used with caution in patients with myasthenia gravis due to the risk of symptom exacerbation. [2, 4, 5, 8]

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- 250 mg tablet
- 250 mg/5mL powder for oral liquid

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates:

- Not routinely used in neonates, discuss with infectious diseases or clinical microbiology.

Oral:

- **Usual dose: ≥ 4 weeks to 18 years:** 7.5 mg/kg/dose (to a maximum dose of 500 mg) 12 hourly.[1, 2, 6, 7]
- **Pertussis: ≥ 4 weeks to 18 years:** 7.5 mg/kg/dose (to a maximum dose of 500 mg) 12 hourly for 7 days.[1-3]
- **Confirmed *Helicobacter pylori* infection: ≥ 1 year to 18 years:** 7.5 mg/kg/dose (to a maximum dose of 500 mg) 12 hourly for 14 days as part of a multidrug eradication schedule. Refer to Enteral infections for recommended eradication schedule.[6, 9]
- **Mycobacterial infections: ≥ 4 weeks to 18 years:** 7.5 -15 mg/kg/dose (to a maximum dose of 500 mg) 12 hourly as part of a multidrug regimen.[1, 2]

Dosing in Overweight and Obese Children: Limited information available, dose based on total body weight.[10]

Renal impairment:

eGFR calculator

- eGFR ≥ 30 mL/minute/1.73m^2: use normal dosing
- eGFR < 30 mL/minute/1.73m^2: 50% dose given 12 hourly. Maximum duration is 14 days.[2, 5, 8]

Hepatic impairment:

- In patients with normal renal function and mild to moderate hepatic dysfunction, no dosage adjustments are required. [5, 6]
- Avoid the use of clarithromycin in severe hepatic impairment if there is concurrent severe renal impairment.[6, 8]

RECONSTITUTION & ADMINISTRATION

Reconstitution - Powder for oral liquid (50 mL bottle):

- Reconstitute with water as follows: tap bottle until all powder flows freely; add the total volume of water as per the manufacturer's instructions for reconstitution and shake to suspend powder.[7]
- Avoid vigorous and/or lengthy shaking of the suspension.[7]
- Discard any remaining suspension after 14 days.[7]

Administration:

- Clarithromycin may be administered without regard to timing of food intake.[4-6]
- Shake the suspension to resuspend particles prior to measuring out the dose.[4, 6]

MONITORING

- Hepatic function, full blood count and renal function should be monitored weekly with prolonged treatment (> 7 days).[6]
- Patients at risk of QT prolongation should have regular electrocardiogram (ECG) monitoring during treatment.[4]

ADVERSE EFFECTS

Common: taste disturbance, reduced appetite, nausea, vomiting, diarrhoea, abdominal pain and cramps, insomnia, vasodilation, vision disorders, candida infections.[2, 8]

Infrequent: rash, headache, dry mouth, burping, epistaxis, tremor, thrombocytosis, haemorrhage. [2, 8]

Rare: Pulmonary infiltration with eosinophilia, torsades de pointes, abnormal dreams, depression, myopathy, renal failure, tooth discolouration, urine discolouration, hypersensitivity (e.g. anaphylaxis, fixed drug eruptions, Stevens-Johnson syndrome, interstitial nephritis), psychiatric disturbances, ototoxicity (e.g. tinnitus, dizziness, hearing loss), *Clostridioides difficile*-associated diarrhoea, cholestatic hepatitis, pancreatitis, prolonged QT interval, blood dyscrasias e.g. thrombocytopenia, agranulocytosis.[2, 8]

STORAGE

- Store the tablets below 25°C.[7]
- Store the liquid (both before and after reconstitution) below 30˚C – do not refrigerate. Discard any remaining suspension 14 days after reconstitution.[7]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **clarithromycin**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Antimicrobial Stewardship Policy

ChAMP Empiric Guidelines and Monographs

KEMH Neonatal Medication Protocols

References

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