



MONOGRAPH

Clarithromycin Monograph - Paediatric

Scope (Staff):	Medical, Nursing, Pharmacy
Scope (Area):	Perth Children's Hospital (PCH)

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

DESCRIPTION	<ul style="list-style-type: none"> • Clarithromycin is a bacteriostatic macrolide antibiotic. It inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit.^(1, 2) • Clarithromycin has a wide spectrum of activity covering Gram positive cocci, Gram negative cocci, <i>Mycoplasma</i>, <i>Chlamydia</i> and some Gram positive and Gram negative anaerobes.⁽³⁾ • It is also active against <i>Bordetella pertussis</i> and is used in combination therapy for the prevention and treatment of <i>Mycobacterium avium</i> complex (MAC) and other non-tuberculosis mycobacterium infections as well as <i>H. pylori</i> eradication.^(1, 3)
INDICATIONS AND RESTRICTIONS	<p>Oral: Unrestricted (green) antibiotic</p> <ul style="list-style-type: none"> • This is not a restricted agent. Follow standard ChAMP guidelines where appropriate.
FORMULATIONS	<p>Available at PCH:</p> <ul style="list-style-type: none"> • 250mg tablet (Klacid[®]) • 250mg/5mL oral suspension for reconstitution (Klacid[®]) <p>Other formulations available:</p> <ul style="list-style-type: none"> • 250mg and 500mg tablets (multiple generic brands)
DOSAGE	<ul style="list-style-type: none"> • 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. <p><u>Neonates:</u></p> <ul style="list-style-type: none"> • Not routinely used in neonates. • Contact infectious disease or clinical microbiology service for advice. <p><u>Oral:</u></p> <ul style="list-style-type: none"> • Usual dose: 1 month to 18 years: 7.5mg/kg/dose (to a maximum dose of 500mg) 12 hourly.^(1, 2, 4, 5) • <i>Helicobacter pylori</i>: 1 year to 18 years: 7.5mg/kg/dose (to a maximum dose of 500mg) 12 hourly as part of a multidrug eradication schedule.⁽³⁾

	<ul style="list-style-type: none"> • Mycobacterial infections: 12.5-15mg/kg/dose (to a maximum dose of 500mg) 12 hourly as part of a multidrug regimen.⁽²⁻⁴⁾
DOSAGE ADJUSTMENT	<p>Dosage adjustment required in renal impairment:</p> <ul style="list-style-type: none"> • Dosage adjustment may be required in cases of impaired renal function (with creatinine clearance of less than 30mL/min).⁽²⁾ • To calculate the estimated glomerular filtration rate (eGFR) use the following formula (also available via the link)⁽³⁾ $\text{eGFR (mL/min/1.73m}^2\text{)} = \frac{36.5 \times \text{height (cm)}}{\text{Serum creatinine (micromol/L)}}$ • CrCl \geq 30mL/minute : normal dosing • CrCl < 30mL/min : 50% dose given 12 hourly. Maximum duration of therapy should be 14 days.^(1, 3-6) <p>Dosage adjustment required in hepatic impairment:</p> <ul style="list-style-type: none"> • In patients with normal renal function and mild to moderate hepatic dysfunction, no dosage adjustments are required. Avoid the use of clarithromycin in severe hepatic impairment.^(2, 4)
RECONSTITUTION	<p>Oral solution (50mL bottle):</p> <ul style="list-style-type: none"> • 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 well to suspend powder.⁽⁷⁾ • Avoid vigorous and/or lengthy shaking of the suspension.⁽⁷⁾ • Discard any remaining suspension after 14 days.⁽⁷⁾
ADMINISTRATION	<ul style="list-style-type: none"> • Clarithromycin may be administered without regard to timing of food intake.⁽⁵⁻⁷⁾ • Shake the suspension to resuspend particles prior to measuring out the dose.⁽⁷⁾
MONITORING	<ul style="list-style-type: none"> • Hepatic function, full blood count and renal function should be monitored weekly with prolonged treatment (> 7 days).^(2, 5)
ADVERSE EFFECTS	<ul style="list-style-type: none"> • Common: taste disturbance, nausea, vomiting, diarrhoea, abdominal pain and cramps, insomnia, headache, skin rash, hyperhidrosis and candida infections. Gastrointestinal side effects are often dose related.^(1, 2, 4) • Rare: Pulmonary infiltration with eosinophilia, torsades de pointes, rash, anorexia, constipation, dry mouth, glossitis, hypersensitivity (e.g. anaphylaxis, fixed drug eruptions, Stevens-Johnson syndrome, interstitial nephritis), psychiatric disturbances, ototoxicity (e.g. tinnitus, dizziness, hearing loss), <i>Clostridium difficile</i>-associated diarrhoea, cholestatic hepatitis, pancreatitis, prolonged QT interval, blood dyscrasias, e.g. thrombocytopenia.^(1, 2, 4)


COMPATIBLE IV FLUIDS	<ul style="list-style-type: none"> • Not applicable
STORAGE	<ul style="list-style-type: none"> • Store the tablets and liquid (both before and after reconstitution) below 30°C. Discard any remaining suspension 14 days after reconstitution.⁽⁷⁾
PRECAUTIONS	<ul style="list-style-type: none"> • Clarithromycin has a number of clinically significant drug interactions, see below for further information.^(1, 5, 7)
CONTRAINDICATIONS	<ul style="list-style-type: none"> • Clarithromycin is contraindicated in patients with history of allergy to clarithromycin or other macrolide antibiotics, and in patients with severe hepatic impairment with coexisting renal impairment.^(2, 7) • Clarithromycin and other macrolide antibiotics have been associated with prolongation of the QT interval and ventricular arrhythmias.^(1, 7)
INTERACTIONS	<p>Clarithromycin has many drug interactions; please consult PCH approved references (such as Clinical Pharmacology), your ward pharmacist or Pharmacy on 6456 0190 (option 1) for more information</p> <ul style="list-style-type: none"> • Clarithromycin may increase the concentration and effect of atorvastatin, simvastatin, cabergoline, calcineurin inhibitors, calcium channel blockers, carbamazepine, colchicine, fentanyl, linezolid and midazolam. Monitor for associated adverse effects, dose reductions may be required.⁽¹⁾ • Clarithromycin may result in oxcarbazepine toxicity if used together; avoid the combination or reduce oxcarbazepine dose and monitor carefully.⁽¹⁾ • Rifampicin and rifabutin may increase the metabolism of clarithromycin thereby reducing the concentration and reducing its antibacterial effect.⁽¹⁾ • Clarithromycin should be used with caution in patients on other medications that may prolong the QT interval.^(1, 7) • Clarithromycin may increase linezolid concentration and risk of toxicity; monitor closely and alter antibiotic regimen or decrease linezolid dose if necessary.⁽¹⁾
COMMENTS	<ul style="list-style-type: none"> • There is often cross resistance seen with macrolide and lincosamide antibiotics.⁽¹⁾
MANUFACTURER SAFETY DATA SHEET (SDS)	<p>To access the Manufacturer SDS for this product, use the following link to ChemAlert.</p>

****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 internal policies, procedures and guidelines
Antimicrobial Stewardship Policy
Neonatal Clinical Care Unit Medication Protocols (KEMH)
ChAMP Empiric Guidelines

References
<ol style="list-style-type: none"> Rossi S, editor. Australian Medicines Handbook 2019. Adelaide, S. Aust.: Australian Medicines Handbook; 2019. Taketomo CK, Hodding JH, Kraus DM, Hodding JH. Pediatric and Neonatal dosage handbook with international trade names index. 23rd ed. Ohio: Lexi-comp; 2017-2018. Antibiotic Writing Group. Therapeutic Guidelines - Antibiotic. West Melbourne: Therapeutic Guidelines Ltd; 2019. Available from: http://online.tg.org.au.pklibresources.health.wa.gov.au/ip/. Paediatric Formulary Committee. BNF for Children: 2019. London: BMJ Group Pharmaceutical Press; 2019. Micromedex 2.0 [Internet]. Truven Health Analytics. 2015 [cited 22/05/2019]. Clinical Pharmacology [Internet]. Elsevier BV. 2019 [cited 22/05/2019]. Available from: http://pklibresources.health.wa.gov.au/login?url=http://www.clinicalpharmacology-ip.com/?id=24317714. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2019. p. 1v. (various pagings).

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