MONOGRAPH

Azithromycin 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]

INDICATIONS AND RESTRICTIONS

Azithromycin has a broad spectrum of activity. It is effective against *Legionella*, *Mycoplasma*, *Chlamydia*, *Salmonella*, *Bordetella pertussis, Rickettsia* species, nontuberculous mycobacteria and some parasites[2]

IV and Oral: Monitored (orange) antibiotic

- If the use is consistent with a standard approved indication, this must be communicated to ChAMP by documenting that indication on all prescriptions (inpatient and outpatient).
- The ChAMP team will review if ongoing therapy is required and/or if the order does not meet ChAMP Standard Indications
- If use is not for a standard approved indication, phone approval must be obtained from ChAMP before prescribing.

CONTRAINDICATIONS

- Hypersensitivity to azithromycin, erythromycin, macrolide or ketolide antibiotic or any component of the formulation.[3, 4]
- Extended courses of azithromycin should NOT be used in patients undergoing haematopoietic stem cell transplant (HSCT) for bronchiolitis obliterans (or similar conditions) due to the increased risk of relapse or death.[4, 5]

PRECAUTIONS

- Azithromycin should be used with caution in patients who have hepatic disease. Discontinue treatment immediately if signs and symptoms of hepatitis and liver dysfunction occur.[6]
- Infantile hypertrophic pyloric stenosis is associated with the use of azithromycin in infants, use with caution in neonates and young infants.[6] The greatest incidence is in the first 2 weeks of life, reducing after this time with no increase in incidence after 7 weeks of age.[1, 3, 4]
- Azithromycin has been shown to prolong the QT interval and should be used with caution in patients at risk of QT prolongation (including concomitant use of other drugs causing QT prolongation and cardiac arrhythmias or cardiac insufficiency). For a list of contributing medications refer to the AMH[1, 3]
- Direct sunlight (UV) exposure should be minimised during azithromycin due to possible photosensitivity reactions.[6]
- IV solutions at a concentration of greater than 2mg/mL may result in infusion-site reactions (pain and local inflammation).[7, 8]
- Each 500mg vial of powder for injection contains a minimum of 114mg (4.96mmol) of sodium. Alternative brands may contain up to 168mg (7.31mmol) of sodium per 500mg vial. Check the sodium content if the patient is sodium restricted.[7]
- Each 200mg/5mL oral suspension contains 3.87grams/5mL of sucrose.[1]

FORMULATIONS

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

- 200mg/5mL oral suspension for reconstitution 15mL
- 500mg tablet
- 500mg powder for injection vial

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Oral:

Bacterial infections (e.g. Mycoplasma pneumonia):

Children ≥ 4 weeks to < 6months:

Not routinely used in children < 6 months of age except in the treatment and prophylaxis of pertussis or for chlamydia conjunctivitis (see recommended doses below).

Oral:

Children ≥ 6 months:

10mg/kg/dose (to a maximum of 500mg) once daily. [1, 9]

Indication specific doses:

Indication	Age	Dose	Duration
Pertussis (treatment and prophylaxis)[1, 9]	≥ 4 weeks to <6months	10mg/kg/dose (to a maximum of 500mg) once daily	5 days
	≥ 6 months	10mg/kg/dose (to a maximum of 500mg) daily for one day then reduce to 5mg/kg/dose (to a maximum of 250mg) daily for a further four days	5 days
Tonsilitis or pharyngitis (high risk beta lactam allergy)[2]	≥ 4 weeks	12mg/kg/dose (to a maximum of 500mg) once daily	5 days
Prevention of exacerbations in Cystic fibrosis, or bronchiectasis[4, 9-13]	Children ≥ 1-6 years	10mg/kg/dose (to a maximum of 250mg) three times a week[14]	Review after 12 months
	Children ≥ 6 years **AND** 25 to <40kg	250mg as a single dose three times a week	Review after 12 months
	Children ≥ 6 years **AND** ≥40kg	500mg as a single dose three times a week.	Review after 12 months
	Children ≥ 1 year	**Alternative dosing:** 30mg/kg/dose (to a maximum of 1.5gram) once weekly.	Review after 12 months
Trachoma and *Chlamydia trachomatis* conjunctivitis[1, 9, 15]	≥ 4 weeks	20mg/kg/dose (to a maximum of 1gram) as a single dose. Repeat doses may be required.	Single dose
Post exposure prophylaxis - Invasive Group A Streptococcal (iGAS) infection[2]	≥ 4 weeks	12mg/kg/dose (to a maximum of 500mg) once daily	5 days
Empiric therapy post sexual assault[16]	≥ 4 weeks	20mg/kg/dose (to a maximum of 1gram) as a single dose	Single dose
	Refer to the Silver book and/or ChAMP Post exposure prophylaxis following non-occupational exposure to body fluids (nPEP) guideline.[16]		

IV:

Usual dose: 10mg/kg/dose (to a maximum of 500mg) once daily.[4, 6] Oral azithromycin therapy is as effective as IV. Consider switching to oral dosing as soon as clinically appropriate.[2]

Renal impairment:

- eGFR calculator (Google Chrome®)
- No dosage adjustment is recommended for creatinine clearance greater than 10mL/min.[6]
- Azithromycin should be used with caution in patients with severe renal impairment (with creatinine clearance of less than 10mL/min) due to the increased azithromycin AUC and Cmax.[2, 6, 10]

Hepatic impairment:

- There is limited information available on the use of azithromycin in patients with hepatic impairment; it appears that no dose adjustments are necessary for mild to moderate impairment.[3, 6] Azithromycin is not recommended in those with severe hepatic impairment.[10]

RECONSTITUTION & ADMINISTRATION

Oral:

- Reconstitute the azithromycin as per the product information. Tap the bottle until all the powder flows freely, add the volume of water for reconstitution and shake vigorously to suspend the powder. Store the reconstituted suspension at less than 30°C and discard any remaining suspension after 10 days. [3]
- Oral tablets and liquid can be administered without regard to food.[3]

IV:

- Reconstitute each 500mg vial with 4.8mL water for injection to prepare a 100mg/mL solution. [7]
- Once reconstituted, further dilute to a final concentration of 1mg/mL to 2mg/mL and infuse over 1 or 3 hours as below.[7]
- Doses higher than 500mg should be given over 1 hour.[8]

Concentration	Duration of infusion
1mg/mL	3 hours
2mg/mL	1 hours
Please note: infusion durations are correct despite the unusual recommendation.	

The infusion of higher concentrations may result in local infusion site reactions (e.g. pain and local inflammation).[7]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Glucose 5%
- Hartmann's
- Sodium chloride 0.45% and 0.9%
- Glucose/ sodium chloride solutions.[7]

Compatible at Y-site:

Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

MONITORING

- Hepatic and haematological function should be monitored weekly with prolonged therapy at treatment doses (i.e. longer than 7 days).[4]
- For patients on an extended prophylactic course of azithromycin, hepatic (LFT's) and haematological (FBC) function should be monitored every three months.[6, 14]

ADVERSE EFFECTS

Common: inflammation and pain at the injection site, nausea, vomiting, diarrhoea, abdominal pain and cramps, reduced appetite, candida infections, insomnia, pancreatitis. [1, 10]

Infrequent: rash, headache[1, 10]

Rare: hypersensitivity reactions (e.g. anaphylaxis, fixed drug eruptions, Stevens-Johnson syndrome, interstitial nephritis), psychiatric disturbances, anxiety, ototoxicity (including tinnitus, dizziness, hearing loss), cholestatic hepatitis, pancreatitis, prolonged QT interval, blood dyscrasias (e.g. thrombocytopenia), photosensitivity.[1, 6, 10]

Note: Infantile hypertrophic pyloric stenosis is associated with the use of azithromycin in infants. The greatest incidence is in the first 2 weeks of life, reducing after this time with no increase in incidence after 7 weeks of age.[1]

STORAGE

- **Vial:** Store below 25°C and protect from light prior to reconstitution.[3, 7]
- **Oral tablet:** Store below 25°C and protect from light and moisture.[3]
- **Oral powder for suspension:** Store dry suspension below 30°C. Once reconstituted, store the suspension below 30°C. Any suspension remaining after 10 days should be discarded.[3]

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 **azithromycin**. 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

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File Path:	W:\Paediatrics\PMH\ChAMP\Monographs\FINALISED\00 Current version 00		
Document Owner:	Head of Department – Infectious Diseases		
Reviewer / Team:	Children's Antimicrobial Management Program Pharmacist		
Date First Issued:	April 2013	**Last Reviewed:**	July 2022
Amendment Dates:	February 2019, July 2021, July 2022	**Next Review Date:**	July 2025
Approved by:	Drugs and Therapeutics Committee	**Date:**	July 2022
Endorsed by:	Drugs and Therapeutics Committee, Chair	**Date:**	July 2022
Standards Applicable:	NSQHS Standards: NSMHS: N/A Child Safe Standards: N/A		

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