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, 2]

INDICATIONS AND RESTRICTIONS

Azithromycin has a broad spectrum of activity. It is effective against *Legionella*, *Mycoplasma*, *Chlamydia*, *Salmonella*, *Bordetella pertussis, Rickettsia* species and nontuberculous mycobacteria. Azithromycin also has some immunomodulatory and anti-inflammatory effects and is used in diffuse panbronchiolitis in Cystic Fibrosis.[2, 3]

Oral: Monitored (orange) antibiotic

Azithromycin is indicated for use as per the indications stipulated in Formulary One. For any other use, phone approval must be obtained from ChAMP before prescribing as per the Children's Antimicrobial Management Program (ChAMP) Policy.

CONTRAINDICATIONS

- Hypersensitivity to azithromycin, erythromycin, macrolide or ketolide antibiotic or any component of the formulation.[2-6]
- Azithromycin is contraindicated in patients with a history of cholestatic jaundice or hepatic dysfunction associated with prior azithromycin use.[3, 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.[2]
- Infantile hypertrophic pyloric stenosis is associated with the use of azithromycin in infants, use with caution in neonates and young 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.[2, 3, 5]
- 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, cardiac arrhythmias, cardiac insufficiency or electrolyte disturbances). For a list of contributing medications refer to the AMH.[2, 4, 5, 7]
- Extended courses of azithromycin should not be used to treat bronchiolitis obliterans (or similar conditions) in patients who have undergone haematopoietic stem cell transplant (HSCT) due to the increased risk of relapse or death.[3, 5, 8]
- IV solutions at a concentration of greater than 2 mg/mL may result in infusion-site reactions (pain and local inflammation).[9]
- Each 200 mg/5 mL oral suspension contains 3.87 grams/5 mL of sucrose.[2, 4]

FORMULATIONS

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

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

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Oral:

Bacterial infections:

Children ≥ 4 weeks to < 6 months:

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:

10 mg/kg/dose (to a maximum of 500mg) once daily. [1, 2]

See indication specific doses on the following page.

Indication specific doses:

Indication	Age	Dose	Duration
Pertussis (treatment and prophylaxis)[1, 2]	≥ 4 weeks to < 6 months	10 mg/kg/dose (to a maximum of 500 mg) once daily	5 days
	≥ 6 months	10 mg/kg/dose (to a maximum of 500 mg) daily for one day then reduce to 5 mg/kg/dose (to a maximum of 250 mg) daily for a further four days	5 days
Tonsilitis or pharyngitis (high risk beta lactam allergy)[10]	≥ 4 weeks	12 mg/kg/dose (to a maximum of 500 mg) once daily	5 days
		Antibiotic therapy is only recommended in selected patient groups (patients aged 2 to 25 years with sore throat in communities with a high incidence of acute rheumatic fever, patients with existing rheumatic heart disease and patients with Scarlet fever). Refer to ChAMP Ear, Nose, Throat and Dental Paediatric Empiric Guidelines for further information.	
Prevention of exacerbations in Cystic fibrosis, or bronchiectasis[1, 3, 11]	Children ≥ 1- <6 years	10 mg/kg/dose (to a maximum of 250 mg) three times a week	Review after 12 months
	Children ≥ 6 years **AND** 25 to < 40kg	250 mg as a single dose three times a week	Review after 12 months
	Children ≥ 6 years **AND** ≥ 40kg	500 mg as a single dose three times a week.	Review after 12 months
	Children ≥ 1 year	**Alternative dosing:** 30 mg/kg/dose (to a maximum of 1.5 gram) once weekly.	Review after 12 months
Trachoma and *Chlamydia trachomatis* conjunctivitis[1, 2, 10]	< 4 weeks	20 mg/kg/dose (to a maximum of 1 gram) once daily. Repeat courses may be required.	3 days
	≥ 4 weeks	20 mg/kg/dose (to a maximum of 1 gram) as a single dose. Repeat doses may be required.	Single dose
Chlamydia trachomatis pneumonia[12]	≥ 4 weeks	20 mg/kg/dose (to a maximum of 500 mg) once daily	3 days
Post exposure prophylaxis - Invasive Group A Streptococcal (iGAS) infection[10]	≥ 4 weeks	12 mg/kg/dose (to a maximum of 500 mg) once daily. Refer to ChAMP Medical Prophylaxis Guidelines for further information.	5 days

Empiric therapy post sexual assault[13]	≥ 4 weeks	20 mg/kg/dose (to a maximum of 1 gram) 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.[13]		
Sexually transmitted infections;[1, 2, 13] - Chlamydial infection - Non-gonococcal genital infection - Gonorrhoea	≥ 4 weeks to < 8 years	10 mg/kg/dose (to a maximum of 1 gram) once daily	5 days
	≥ 8 years to < 12 years	20 mg/kg/dose (to a maximum of 1 gram) as a single dose	Single dose
	≥ 12 years	1 gram as a single dose	Single dose
	Treatment of gonorrhoea requires the addition of a single ceftriaxone dose. Refer to the Silver book or Sexually Transmitted Infections (PIC) for further information.		

IV:

- **Usual dose:** 10 mg/kg/dose (to a maximum of 500 mg) once daily.[5]
- IV therapy should be reserved for patients unable to tolerate the oral formulation. Oral azithromycin therapy is as effective as IV due to extensive distribution and high intracellular concentration. Consider switching to oral dosing as soon as clinically appropriate.[10]

Renal impairment:

- eGFR calculator
- No dosage adjustment is recommended for creatinine clearance greater than 10 mL/minute/1.73 m^2.[3, 7]
- Azithromycin should be used with caution in patients with severe renal impairment (with creatinine clearance of less than 10 mL/minute/1.73 m^2) due to the increased azithromycin AUC and Cmax.[5]

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. Azithromycin is not recommended in those with severe hepatic impairment.[3, 5]

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.[4]
- Oral tablets and liquid can be administered without regard to food.[5]

IV:

- Reconstitute each 500 mg vial with 4.8 mL water for injection to prepare a 100 mg/mL solution.[4, 5, 9]
- Once reconstituted, further dilute to a final concentration of 1 mg/mL to 2 mg/mL and infuse over 1 or 3 hours as below.[9]

Concentration	Duration of infusion
1 mg/mL	3 hours
2 mg/mL	1 hour
Please note: infusion durations are correct despite the unusual recommendation.[2, 5, 9, 14]	

The infusion of higher concentrations may result in local infusion site reactions (e.g. pain and local inflammation).[9]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Glucose 5%
- Hartmann's
- Sodium chloride 0.45% and 0.9%
- Glucose/ sodium chloride solutions.[4, 9]

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).[5]
- For patients on an extended prophylactic course of azithromycin, hepatic (LFT's) and haematological (FBC) function should be monitored every three months.[3, 5]
- Hearing assessment should be conducted in patients on treatment doses for prolonged therapy (greater than 1 month) as hearing loss has been reported with long term treatment.[3, 15]
- Consider ECG in patients at risk of QT prolongation.[3, 5]
- Neonates and young children should be monitored for vomiting and irritability with feeds due to the risk of hypertrophic pyloric stenosis.[2, 7]

ADVERSE EFFECTS

Common: inflammation and pain at the injection site, nausea, vomiting, diarrhoea, abdominal pain and cramps, reduced appetite, candida infections, insomnia, paraesthesia. [2, 7]

Infrequent: rash, headache[2]

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, torsades de points, multi-organ hypersensitivity syndrome, blood dyscrasias (e.g. thrombocytopenia, leucopenia, neutropenia), photosensitivity, constipation.[2, 7]

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.[2]

STORAGE

- **Vial:** Store below 25°C and protect from light prior to reconstitution.[4, 9]
- **Oral tablet:** Store below 25°C and protect from light and moisture.[4]
- **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.[4]

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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