MONOGRAPH

Ciprofloxacin 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

Quinolone antibiotic.[1, 2]

INDICATIONS AND RESTRICTIONS

- Ciprofloxacin is active against a wide range of Gram negative bacteria including *Pseudomonas aeruginosa*, *Haemophilus influenza*, enteric Gram negative rods, Gram negative cocci and intracellular organisms.[3]
- There is increasing resistance to ciprofloxacin and other quinolone antibiotics and use should be reserved for infections resistant to other antibiotics.[2]

Oral: Monitored (orange) antibiotic

Ciprofloxacin 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 Antimicrobial Stewardship Policy.

IV: Restricted (red) antibiotic

ChAMP approval is required prior to prescribing.

CONTRAINDICATIONS

- Hypersensitivity to ciprofloxacin, other quinolones (including nalidixic acid) or any component of the formulation.[4-6]
- Ciprofloxacin is associated with a risk of haemolysis in individuals with G6PD deficiency and should be avoided in these patients.[7, 8] Refer to: Glucose-6-Phosphate Dehydrogenase Deficiency Guideline.
- Ciprofloxacin is contraindicated in patients with a history of tendon disorders related to quinolone use.[2, 9]
- Ciprofloxacin with hydrocortisone ear drops (Ciproxin® HC drops) are contraindicated in known or suspected tympanic perforation and in latex allergy due to the latex content of the dropper.[4, 9]

PRECAUTIONS

- Although animal studies have suggested a risk of damage to developing cartilage with quinolones, evidence supporting sustained injury to developing joints in humans is lacking at this time.[9]
- Extended use of quinolones is associated with an increased risk of tendonitis and tendon rupture in all ages.[4]
- The use of systemic quinolones should be avoided in patients with an existing aortic aneurysm or in patients at an increased risk for developing an aortic aneurysm (e.g. Marfan syndrome, Ehlers-Danlos syndrome).[4]
- Ciprofloxacin is associated with cases of QT prolongation. Precaution should be taken when using ciprofloxacin with concomitant medicines that can result in prolongation with the QT interval (e.g. class IA or III antiarrhythmics) or in patients with risk factors for torsade de pointes (e.g. known QT prolongation, uncorrected hypokalaemia).[4, 9]
- Avoid concurrent use of alkalinising agents and maintain adequate hydration to avoid crystalluria.[1, 5]
- Ciprofloxacin may lower the seizure threshold in people with or without epilepsy or a history of central nervous system (CNS) disorders; concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) may further increase this risk.[4]

FORMULATIONS

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

- 250 mg, 500 mg and 750 mg tablets.
- 200 mg/100 mL fluid for infusion
- Ciprofloxacin 0.3% Ear drops
- Ciprofloxacin 0.3% Eye drops
- Ciprofloxacin 0.2% with Hydrocortisone 1% ear drops

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Oral: ≥ 4 weeks to 18 years

Where possible, doses should be rounded to the nearest portion of a tablet to facilitate oral administration.

- **Usual dose**: 10-15 mg/kg/dose (to a maximum 500 mg) given 12 hourly.[2, 10]
- **Severe infections:** 20 mg/kg/dose (to a maximum of 750 mg) given 12 hourly.[2, 9, 10]
- **Cystic fibrosis**: 15-20 mg/kg/dose (to a maximum of 750 mg) given 12 hourly.[2, 10]

Consider the following dose bands for patients with Cystic Fibrosis:

Weight	Dose
< 6kg	20mg/kg twice daily (consider syrup formulation)
6 kg to < 8.4 kg	125mg twice daily
8.4 kg to <11 kg	187.5mg twice daily
11 kg to <14 kg	250mg twice daily
14 kg to <17 kg	312.5mg twice daily
17 kg to <22 kg	375mg twice daily
22 kg to <28 kg	500mg twice daily
28 kg to <35 kg	625mg twice daily
≥35 kg	750mg twice daily

Post exposure prophylaxis – *Neisseria meningitidis* (Meningococcal infection):

- Child ≥ 4 weeks to < 5 years: 125 mg as a single dose.[9]
- Child ≥ 5 years to < 12 years: 250 mg as a single dose.[9]
- Child ≥ 12 years: 500 mg as a single dose[9, 10]

IV: ≥ 4 weeks to 18 years

Ciprofloxacin is well absorbed orally, the IV route is generally reserved for situations where oral therapy is not possible.[2]

- **Usual dose:** 10-15 mg/kg/dose (to a maximum 400 mg) given 12 hourly.[2, 5, 10]
- **Severe infections:** 10 mg/kg/dose (to a maximum of 400 mg) given 8 hourly.[2, 9, 10]
- **Cystic fibrosis:** 10 mg/kg/dose (to a maximum of 400 mg) given 8 hourly.[2, 10]

Renal impairment:

eGFR calculator

eGFR	Dose recommendation[5, 11]	
	Intravenous	Oral
≥ 30 mL/minute/1.73 m^2	Usual dosing, no adjustment required	Usual dosing, no adjustment required[5, 11]
10-29 mL/minute/1.73 m^2	10-15 mg/kg/dose (to a maximum of 400 mg) every 18 hours	10-15 mg/kg/dose (to a maximum of 500 mg) every 18 hours
< 10 mL/minute/1.73 m^2	10-15 mg/kg/dose (to a maximum of 400 mg) every 24 hours	10-15 mg/kg/dose (to a maximum of 500 mg) every 24 hours

Hepatic impairment:

- No dosage adjustments are necessary in stable hepatic dysfunction.[5]

ADMINISTRATION

- Prior to administration (of either IV or oral ciprofloxacin), ensure the patient is well hydrated to reduce the risk of crystalluria.[2, 5]

IV infusion:

- Give undiluted or dilute to 1 mg/mL and infuse over 60 minutes.[1, 2, 5]
- Infusion over 60 minutes reduces the risk of venous irritation (e.g. burning, pain, erythema and swelling).[1]

Oral:

- Best absorbed on an empty stomach, one hour before or two hours after food.[2, 11]
- Separate doses from iron, calcium, zinc, antacids and dairy products by at least 2 hours.[2, 5]
- Doses should be rounded to the nearest portion of a tablet and may be crushed and mixed with water, juice or a small amount of apple puree, jam, or chocolate sauce for administration.
- **Note:** Oral ciprofloxacin is extremely unpalatable.[12]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Glucose 5% and 10%
- Sodium chloride 0.9%
- Ringer's
- Hartmann's[1]

Compatible at Y-site:

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

MONITORING

- Renal, hepatic and haematological function should be monitored weekly with prolonged therapy (i.e. longer than 7 days).[5]
- Patients should be instructed to ensure adequate fluid intake and to avoid urinary alkalinisers due to the risk of crystalluria.[1, 2, 10]
- Patients should be counselled to contact the prescriber if there is any tendon soreness, inflammation or any signs of peripheral neuropathy (numbness or tingling of the fingers or toes).[2]

ADVERSE EFFECTS

Common: rash, nausea, vomiting, diarrhoea, abdominal pain, dyspepsia, itch.[2]

Infrequent: headache, dizziness, insomnia (including abnormal dreams), depression, restlessness, tremors, arthralgia, arthritis, myalgia, tendonitis, interstitial nephritis, raised liver enzymes, erythema, itch, pain or thrombophlebitis at IV infusion site, sensory disturbance (hearing, taste or smell).[2]

Rare: blood dyscrasias, seizures, psychotic reactions, anaphylaxis, *Clostridioides difficile*-associated disease, tendon rupture (especially of the Achilles tendon), Stevens-Johnson syndrome, fixed drug eruption, hepatitis, peripheral neuropathy, phototoxicity, prolongation of QT interval, crystalluria, hyper- or hypoglycaemia, aortic aneurysm or dissection, angioedema, toxic epidermal necrolysis.[2]

STORAGE

IV: Store below 25°C. Protect from light, do not refrigerate or freeze.[1]

Tablets: Store below 25°C.[4]

Eye and ear drops: Store below 25°C. Protect from light, do not refrigerate or freeze. Discard 4 weeks after opening.[4]

Ciprofloxacin 0.2% with Hydrocortisone 1% ear drops: Store below 25°C. Protect from light, do not refrigerate or freeze. Discard 14 days after opening.[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 **ciprofloxacin**. 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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