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

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]
- It has minimal activity against anaerobes and Gram positive organisms. In these cases, alternative agents should be used.[3]
- There is increasing resistance to ciprofloxacin and other quinolone antibiotics and use should be reserved for infections resistant to other antibiotics.[1]

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.

IV: Restricted (red) antibiotic

ChAMP approval is required prior to prescription.

CONTRAINDICATIONS

- Hypersensitivity to ciprofloxacin, other quinolones (including nalidixic acid) or any component of the formulation.[1, 2, 4]
- Ciprofloxacin is associated with a risk of haemolysis in individuals with G6PD deficiency and should be avoided in these patients.[4, 5] Refer to: Glucose-6-Phosphate Dehydrogenase Deficiency Guideline.
- Ciprofloxacin is contraindicated in patients with a history of tendon disorders related to quinolone use.[2, 5]
- Ciprofloxacin with hydrocortisone ear drops (Ciproxin® HC drops) are contraindicated in known or suspected tympanic perforation.[6]
- Ciprofloxacin with hydrocortisone ear drops (Ciproxin® HC drops) dropper contains latex – avoid in latex allergy.[6]

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.[3]
- Extended use of quinolones is associated with an increased risk of tendonitis and tendon rupture in all ages.[6]
- 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, 6]
- 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).[2-4, 6]
- Avoid concurrent use of alkalinising agents and maintain adequate hydration to avoid crystalluria.[1, 2, 7]
- 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.[1, 4, 6]
- The different brands of IV ciprofloxacin contain varying amounts of sodium (e.g. Ciproxin® brand contains 15.4mmol of sodium per 200mg/100mL) consider alternative brands if the patient is sodium restricted.[7]

FORMULATIONS

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

- 250mg, 500mg and 750mg tablets.
- 200mg/100mL 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

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.[1]

- **Usual dose:** 10-15mg/kg/dose (to a maximum 400mg) given 12 hourly[1, 5, 8]
- **Severe infections:** 10mg/kg/dose (to a maximum of 400mg) given 8 hourly.[1, 5, 8]
- **Cystic fibrosis:** 10mg/kg/dose (to a maximum of 400mg) given 8 hourly.[1, 5, 8]

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**: 10-15mg/kg/dose (to a maximum 500mg) given 12 hourly[8]
- **Severe infections:** 20mg/kg/dose (to a maximum of 750mg) given 12 hourly[8]
- **Cystic fibrosis**: 15-20mg/kg/dose (to a maximum of 750mg) given 12 hourly.[8]

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

- Child ≥ 4 weeks to < 5 years: 125mg as a single dose
- Child ≥ 5 years to < 12 years: 250mg as a single dose
- Child ≥ 12 years: 500mg as a single dose

Renal impairment:

eGFR calculator

- CrCl > 30mL/minute: Usual dosing, no adjustment.
- CrCl 10-29mL/minute: 10-15mg/kg/dose IV/Oral every 18 hours (note maximum dose limits above).[4]
- CrCl <10mL/minute: 10-15mg/kg/dose IV/Oral every 24 hours (note maximum dose limits above).[4]

Hepatic impairment:

- No dosage adjustments are necessary in stable hepatic dysfunction.[2, 4]

ADMINISTRATION

- Prior to administration, ensure the patient is well hydrated to reduce the risk of crystalluria.[1, 7]

IV infusion:

- Give undiluted or dilute to 1mg/mL and infuse over 60 minutes.[4, 7]
- Infusion over 60 minutes reduces the risk of venous irritation (e.g. burning, pain, erythema and swelling).[4]

Oral:

- Best absorbed on an empty stomach, one hour before or two hours after food.[4, 8]
- Separate doses from iron, calcium, zinc, antacids and dairy products by at least 2 hours.[2, 8]
- 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 or jam for administration.
- **Note:** Ciprofloxacin is extremely unpalatable[9]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Glucose 5% and 10%
- Sodium chloride 0.9%
- Ringer's
- Hartmann's[7]

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).[2, 4]
- Patients should be instructed to ensure adequate fluid intake and to avoid alkaline urine due to the risk of crystalluria.[7]
- 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).[1]

ADVERSE EFFECTS

Common: rash, nausea, vomiting, diarrhoea, abdominal pain, dyspepsia..[1, 4, 5]

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 (taste or smell)[1, 4, 5]

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, photosensitivity, prolongation of QT interval, crystalluria, hyper- or hypoglycaemia aortic aneurysm or dissection.[1, 4, 5]

STORAGE

IV: Store below 25°C. Protect from light, do not refrigerate or freeze.[7]

Tablets: Store below 25°C. Protect from light, do not refrigerate or freeze.[6]

Eye and ear drops: Store below 25°C. Protect from light, do not refrigerate or freeze. Discard 4 weeks after opening.[6]

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.[6]

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

References

1. Rossi S, editor. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2021.
2. Clinical Pharmacology [Internet]. Elsvier BV. 2021 [cited 15/12/2021]. Available from: http://www.clinicalpharmacology-ip.com.pklibresources.health.wa.gov.au/default.aspx.
3. Antibiotic Writing Group. Therapeutic Guidelines - Antibiotic. West Melbourne: Therapeutic Guidelines Ltd; 2019. Available from: https://tgldcdp-tg-org-au.pklibresources.health.wa.gov.au/etgAccess.
4. Ciprofloxacin Pediatric Drug Information [Internet]. Lexicomp. 2021 [cited 15/12/2021].
5. Paediatric Formulary Committee. BNF for Children: 2021. London: BMJ Group Pharmaceutical Press; 2021.
6. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2021. p. 1v. (various pagings).

7. Symons K. Ermer J. (editors). Australian injectable drugs handbook. Collingwood: The Society of Hospital Pharmacists of Australia; 2020.
8. Royal Australian College of General Practitioners, Pharmaceutical Society of Australia, Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists. AMH: Children's Dosing Companion. Adelaide: Australian Medicines Handbook Pty Ltd; 2020.
9. Abbotsford J, Goff Z, Foley DA, Yeoh DK, Brophy-Williams S. A matter of taste: Results of antibiotic suspension tasting among paediatric doctors. J Paediatr Child Health. 2021;57(1):161-2.

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