MONOGRAPH

Norfloxacin Monograph - Paediatric

Scope (Staff): Medical, Pharmacy, Nursing,
Scope (Area): All Clinical Areas – Perth Children’s Hospital

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

INDICATIONS AND RESTRICTIONS

- Due to the emergence of resistance, norfloxacin should be reserved for infections where alternative agents are ineffective or contraindicated.\(^{(1)}\)
- Norfloxacin is indicated as directed therapy in complicated urinary tract infections or acute infectious diarrhoea (e.g. Campylobacter enteritis).\(^{(1-3)}\)

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 norfloxacin, other quinolone antibiotics (including nalidixic acid) or any component of the formulation.\(^{(1, 4-6)}\)
- Norfloxacin should be avoided in Glucose-6-phosphate-dehydrogenase deficient individuals as there is an associated risk of haemolysis.\(^{(1, 5)}\)
- Norfloxacin is contraindicated in patients with a history of tendon disorders related to quinolone use.\(^{(1, 6)}\)
- Norfloxacin should be avoided in patients with a history of peripheral neuropathy. Peripheral neuropathy due to norfloxacin may be irreversible.\(^{(1, 6)}\)
- Norfloxacin should be avoided in patients with myasthenia gravis, as it may worsen muscle weakness.\(^{(1)}\)

### PRECAUTIONS
- Use of quinolones such as norfloxacin is associated with an increased risk of tendonitis and tendon rupture in all ages. The risk is increased in patients with concurrent corticosteroid use, kidney, heart or lung transplant, renal impairment, hyperparathyroidism, musculoskeletal disorders, diabetes or athletes in training.\(^{(1, 6)}\) Stop norfloxacin treatment at the first sign of tendon pain, inflammation or peripheral neuropathy.\(^{(1)}\)
- Avoid concurrent use of alkalinising agents and maintain adequate hydration to avoid crystalluria. Crystalluria is more likely in patients taking high doses.\(^{(4-6)}\)
- Norfloxacin may lower the seizure threshold in patients with epilepsy or a history of seizure disorders, avoid use.\(^{(1, 6)}\)
- Advise patient to avoid sun exposure, wear protective clothing and apply sunscreen while taking norfloxacin.\(^{(5, 6)}\)
- Norfloxacin should be used with caution in patients with cardiac arrhythmias or other cardiac disease that predisposes to cardiac arrhythmias. Fluoroquinolones have the potential to cause QT prolongation and possible torsade de pointes.\(^{(4)}\)

### FORMULATIONS
Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:
- 400mg tablets
  Imprest location: Formulary One

### DOSAGE & DOSAGE ADJUSTMENTS
**Neonates:** Norfloxacin is not routinely use in neonates.

**Infants and Children:**
- **<6 months old:** Contact Infectious Diseases. Norfloxacin is not routinely used in infants <6 months of age.
- **≥ 6 months old:** 7.5 to 10mg/kg/dose (to a maximum of 400mg) 12 hourly.\(^{(1, 3)}\)
### Renal impairment:
- **eGFR calculator**
  
  - eGFR >30mL/minute: Normal dose
  - eGFR ≤ 30mL/minute: 100% of the standard dose once daily.\(^{(1, 4, 5)}\)

### Hepatic impairment:
- Specific guidelines for dosage adjustments in patients with hepatic impairment are not available. Cases of hepatitis have been reported with norfloxacin.\(^{(4)}\)

### ADMINISTRATION
- Prior to administration, ensure the patient is well hydrated to reduce the risk of crystalluria.\(^{(1, 4, 5)}\)
- Best taken on an empty stomach, 1 hour before or 2 hours after food, with plenty of water.\(^{(1)}\)
- Separate doses from iron, calcium, zinc, antacids and dairy products by 2 hours.\(^{(1)}\)

### COMPATIBILITY
Not applicable

### MONITORING
- For prolonged therapy (infections requiring more than 7 days of treatment), renal, hepatic and haematological function should be monitored weekly.\(^{(4)}\)
- Consider urinalysis to detect crystalluria for patients on high doses.\(^{(6)}\)

### ADVERSE EFFECTS
**Common:** rash, itch, nausea, vomiting, diarrhoea, abdominal pain, dyspepsia\(^{(1)}\)

**Infrequent:** headache, dizziness, insomnia, depression, restlessness, tremors, arthralgia, arthritis, myalgia, tendonitis, interstitial nephritis, raised liver enzymes, sensory disturbances.\(^{(1)}\)

**Rare:** blood dyscrasias, seizures, psychotic reactions, angioedema, anaphylaxis, *Clostridium difficile*-associated disease, tendon rupture (onset may be rapid or take some months), Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatitis, peripheral neuropathy (may be irreversible), aortic rupture or dissection.\(^{(1)}\)

### STORAGE
Store tablets below 25˚C.\(^{(5)}\)

### 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 norfloxacin. 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**

### References


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**Healthy kids, healthy communities**

Compassion  
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