## Norfloxacin Monograph - Paediatric

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<tr>
<th>Scope (Staff):</th>
<th>Clinical Staff – Medical, Nursing, Pharmacy</th>
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<td>Scope (Area):</td>
<td>PCH</td>
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This document should be read in conjunction with this **DISCLAIMER**

### DESCRIPTION
Norfloxacin is a bactericidal fluoroquinolone antibiotic which inhibits bacterial DNA synthesis by blocking DNA gyrase and topoisomerase IV. (1) There is increasing resistance to norfloxacin and other fluoroquinolones and use should be reserved for infections only resistant to other antibiotics. (1, 2)

Norfloxacin is active against a wide range of Gram negative bacteria including *Pseudomonas aeruginosa*, *Escherichia coli*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia* species, *Serratia* species, *Acinetobacter* species, *Klebsiella* species, *Morganella* species and enteric Gram negative rods. Excluding *Enterococcus faecalis*, norfloxacin is shown to have minimal activity against anaerobes and Gram positive organisms. In these cases, alternative antibiotics should be used. (1-3)

### INDICATIONS AND RESTRICTIONS
**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.

Norfloxacin has poor systemic bioavailability and is reserved for urinary tract infections (not first line) and enteric infections (e.g. travellers’ diarrhoea and Shigella). (1)

### CONTRAINDICATIONS
Norfloxacin is contraindicated in patients with serious allergic reactions or other hypersensitivity to norfloxacin or quinolones including nalidixic acid. (1, 4, 5)

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)
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### PRECAUTIONS

Extended use of quinolones such as norfloxacin is associated with an increased risk of tendonitis and tendon rupture in all ages. Animal studies have suggested that the use of fluoroquinolones in children may increase the risk of developing erosions in the cartilage of weight bearing joints and other signs of arthropathy. This has not been supported by a number of paediatric studies. Stop norfloxacin treatment at the first sign of tendon pain, inflammation or peripheral neuropathy.

Avoid concurrent use of alkalinising agents and maintain adequate hydration to avoid crystalluria.

Norfloxacin may lower the seizure threshold in patients with epilepsy or a history of seizure disorders.

Advise patient to avoid sun exposure, wear protective clothing and use sunscreen while taking norfloxacin.

### FORMULATIONS

**Available at PCH:**
- 400mg tablets (Nufloxib)

**Other formulations available:**
- 400mg scored tablets (Roxin)

### DOSAGE

The doses listed below fall within the standard range. Higher doses may be prescribed for certain situations in consultation with an infectious diseases or clinical microbiology consultant.

**Oral:**
- **Neonates and children less than 6 months old:** Not routinely used in neonates or children less than 6 months old. Contact infectious diseases or clinical microbiology service for advice.
- **Children:** 6 months to 18 years: oral 7.5 to 10 mg/kg/dose (to a maximum of 400 mg) twice daily.

### DOSAGE ADJUSTMENT

**Dosage adjustment required in renal impairment:**
- Dosage adjustment may be required in cases of impaired renal function (with creatinine clearance of less than 30mL/min).
- To calculate the estimated glomerular filtration rate (eGFR) use the following formula:
  
  $$
  \text{eGFR (mL/min/1.73m}^2\text{)} = \frac{36.5 \times \text{height (in cm)}}{\text{Serum creatinine (micromol/L)}}
  $$

  eGFR >30mL/minute: Normal dose
  
  eGFR ≤ 30mL/minute: 100% of dose once daily.

**Dosage adjustment required in hepatic impairment:**
- Specific guidelines for dosage adjustments in patients with hepatic impairment are not available.
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<th>RECONSTITUTION</th>
<th>Not applicable</th>
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| ADMINISTRATION | Prior to administration, ensure the patient is well hydrated to reduce the risk of crystalluria.(1, 5)  
Best taken on an empty stomach 1 hour before or 2 hours after meals with plenty of water.(1)  
Separate doses from iron, calcium, zinc, antacids and milk by 2 hours.(1) |
| MONITORING | For prolonged therapy (infections requiring more than 7 days of treatment), renal, hepatic and haematological function should be monitored weekly.(4, 7) |
| ADVERSE EFFECTS | Common rash, itch, nausea, vomiting, diarrhoea, abdominal pain, dyspepsia(1)  
Rare headache, dizziness, insomnia, depression, restlessness, tremors, arthralgia, arthritis, myalgia, tendonitis, interstitial nephritis, raised liver enzymes, blood dyscrasias, seizures, psychotic reactions, angioedema, anaphylaxis, Clostridium difficile-associated disease, tendon rupture, especially of the Achilles tendon (onset may be rapid or take some months), Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatitis, peripheral neuropathy (may be irreversible).(1) |
| COMPATIBLE FLUIDS | Not applicable |
| STORAGE | Store tablets below 25˚C.(5) |
| INTERACTIONS | Norfloxacin interacts with other medications; please consult PCH approved references (such as Clinical Pharmacology), your ward pharmacist or Pharmacy on extension 60190 for more information.  
- Administration of calcium, iron, dairy products or antacids at the same time as Norfloxacin reduces the absorption and effect of Norfloxacin. Doses should be separated by at least 2 hours.(1, 5)  
- Norfloxacin may inhibit the metabolism of theophylline and aminophylline thereby increasing its concentration. The dosage of theophylline may require adjustment.(5)  
- Norfloxacin may induce seizures in people with epilepsy or a history of CNS disorders; use with caution with other medications that may cause seizures.(5)  
- Norfloxacin should not be used in conjunction with nitrofurantoin. Nitrofurantoin may antagonise the antibacterial effect of norfloxacin in the urinary tract.(5)  
- The use of Norfloxacin and ciclosporin (cyclosporin) can result in |
increased ciclosporin (cyclosporin) levels. Ciclosporin (cyclosporin) levels should be monitored.(5)

- Norfloxacin may increase the effect of warfarin, increasing risk of bleeding. Monitor the INR and adjust the warfarin dose as necessary.(5)
- The use of Norfloxacin and NSAID's may increase the risk of seizures.(4, 5)

**COMMENTS**

Norfloxacin has poor bioavailability at 30-40% and a half-life of 3-4 hours.(4, 5)

**MANUFACTURER SAFETY DATA SHEET (SDS)**

To access to the Manufacturer SDS for this product, use the following link to ChemAlert.

**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**

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**Related internal policies, procedures and guidelines**

- Antimicrobial Stewardship Policy
- Resources

**ChAMP empiric guidelines and monographs**

**References**

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