MONOGRAPH

Moxifloxacin 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.[1-4]

INDICATIONS AND RESTRICTIONS

- Moxifloxacin is active against Gram-positive aerobic bacteria (including *staphylococci* and *streptococci*, with variable activity against Methicillin Resistant *Staphylococcus aureus* (MRSA)) and a wide range of Gram-negative aerobes, except for *Pseudomonas aeruginosa*. It has good activity against anaerobes and atypical bacteria causing pneumonia.[5] Moxifloxacin has excellent bioavailability and good tissue penetration including CNS.
- Moxifloxacin should be reserved for the treatment of infections resistant to other antibiotics.[5]

IV and Oral: Protected (red) antibiotic

ChAMP approval is required prior to prescription.

CONTRAINDICATIONS

- Hypersensitivity to moxifloxacin, other quinolones (including nalidixic acid) or any component of the formulation.[1, 4, 6-8]
- Moxifloxacin prolongs the QT interval and as such is contraindicated in patients with known QT prolongation, patients with uncorrected hypokalaemia and patients receiving certain antiarrhythmic agents, or in combination with other QT prolonging agents.[1, 3, 4, 6, 8, 9]

PRECAUTIONS

- Moxifloxacin should be used with caution in patients with a history of tendon damage from a quinolone antibiotic. It should be discontinued immediately in any patient who develops tendinopathy or tendon rupture. [1, 4, 6, 9]
- The use of systemic quinolones should be avoided in patients with an existing aortic aneurysm or dissection or in patients at an increased risk for developing an aortic aneurysm (e.g. Marfan syndrome, Ehlers- Danlos syndrome).[1, 4, 7, 9]
- Moxifloxacin is associated with a risk of haemolytic anaemia in individuals with Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency and should be avoided in these patients.[1, 4, 9]
- Moxifloxacin may lower the seizure threshold in people with or without epilepsy or a history of CNS disorders, concomitant use of non-steroidal anti-inflammatory drugs (NSAIDs) may further increase this risk.[1, 4, 6, 9, 10]
- Moxifloxacin is associated with neurotoxicity, including peripheral neuropathy, psychiatric disorders or worsening of psychiatric symptoms. Patients should be instructed to cease therapy at the earliest sign of neuropathy or any psychiatric side effects which may be irreversible.[1, 4, 6, 8, 9]
- Moxifloxacin should be avoided in patients with myasthenia gravis as it may exacerbate the associated muscle weakness.[5, 6, 9]
- Disturbances in blood glucose levels have been reported in patients with diabetes on oral hypoglycaemic agents or insulin. More frequent monitoring of blood glucose levels are recommended.[4, 6]
- Moxifloxacin has been associated with phototoxicity, patients should be instructed to avoid excessive UV exposure.[4, 6]
- The IV formulation contains significant sodium content which is variable for different brands:
    - Each 400 mg (250 mL bag) of the Avelox® brand contains 34 mmol of sodium.[3, 8]
    - Each 400 mg (250 mL bag) of the Moxifloxacin Kabi® brand contains 54.4 mmol of sodium.[3, 8]

FORMULATIONS

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

- 400 mg tablet
- 400 mg/250 mL fluid for infusion

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates and children under 3 months of age:

- Not routinely used in neonates and children under 3 months of age, contact infectious diseases or clinical microbiology consultants for advice.(1)

IV: ≥ 3 months to 18 years:

- 10 mg/kg/dose (to a maximum of 400 mg) once daily.(2)
- Moxifloxacin has good oral bioavailability (90%) – consider switching to oral dosing as soon as clinically appropriate.(3, 8)

Oral: ≥ 3 months to 18 years:

- **Usual dose:** 10 mg/kg/dose (to a maximum of 400 mg) once daily.(2)
- **Multi-drug resistant tuberculosis:** 10-15 mg/kg/dose (to a maximum of 400 mg) once daily.(2, 6, 8)
- Doses should be rounded to the nearest half or quarter of a tablet.

Dosing in Overweight and Obese Children: Minimal information available, dose on measured body weight.(11, 12)

Renal impairment:

- No dosage adjustments are required for patients with renal impairment.(4, 6)

Hepatic impairment:

- No dosage adjustments are required for patients with hepatic impairment. Although moxifloxacin should be used with caution in severe hepatic disease as the associated metabolic disturbances may increase the risk of QT prolongation.(4, 6)

ADMINISTRATION

IV infusion:

- Administer undiluted over 60 minutes.(1-4, 6-8, 10)
- Do not administer at a faster rate due to the risk of QT prolongation.(4, 6)

Oral:

- May be given without regard to food intake.(4, 6)
- Separate doses of moxifloxacin from calcium, iron, zinc and antacids containing magnesium or aluminium by at least 2 hours prior and 4 hours post dose.(1, 4, 6, 8)
- Doses should be rounded to the nearest portion of a tablet and may be dispersed in water. The tablet will disperse in approximately 4 minutes. This mixture should be shaken well as the tablet coating may adhere to the side of the enteral syringe.(4)
- **Note:** May be dispersed in water and mixed in a small amount of yoghurt or apple puree to disguise the taste as it is extremely unpalatable. Chocolate syrup can be given before and after the dose which may assist in masking the bitter taste.(4)

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Glucose 5% and 10%
- Sodium chloride 0.9%
- Hartmann's
- Ringer's[3, 10]

Compatible at Y-site:

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

MONITORING

- Hepatic function and creatinine should be monitored weekly with prolonged therapy (i.e. longer than 7 days).[2, 6]
- ECG should be performed in patients with severe hepatic impairment, those on prolonged therapy or those at risk of QT prolongation.[2, 4, 7]
- Blood glucose should be monitored regularly in diabetic patients due to the risk of hyper or hypoglycaemia.[6, 7]
- Patients should be instructed to report any joint or tendon pain, especially in those on prolonged courses.[4, 7, 8]

ADVERSE EFFECTS

Common: dizziness, injection site reactions, rash, itch, nausea, vomiting, diarrhoea, abdominal pain, dyspepsia.[1]

Infrequent: prolongation of QT interval, ventricular tachyarrhythmias, palpitations, headache, insomnia, depression, restlessness, tremors, arthralgia, arthritis, tendonitis, raised liver function tests (LFTs), interstitial nephritis, sensory disturbances (e.g. changes in hearing, taste or vision).[1]

Rare:, multi-organ hypersensitivity syndrome (e.g. DRESS), hepatitis, torsades de points, aortic aneurysm or dissection, aortic or mitral regurgitation, blood dyscrasias, hyper or hypoglycaemia, seizures, psychotic reactions, anaphylaxis, *Clostridioides difficile*-associated diarrhoea, tendon rupture, peripheral neuropathy, angioedema, Stevens Johnson syndrome, toxic epidermal necrolysis.[1]

STORAGE

- **Tablets:** Store below 25˚C.[8]
- **IV:** Solution should be stored between 15˚C and 30˚C. Do not refrigerate as the solution precipitates at < 15˚C, however it will redissolve at room temperature.[3, 8]

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 **moxifloxacin**. 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

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