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)

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. It has good activity against anaerobes and atypical bacteria causing pneumonia. Moxifloxacin does not have good Pseudomonas cover.⁽²⁾
- Moxifloxacin is used in the management of some mycobacterial infections and post penetrating eye injury.⁽²⁾
- Moxifloxacin should be reserved for the treatment of infections resistant to other antibiotics.

IV: Restricted (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, 3, 4)
- 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. (2-4)

PRECAUTIONS

- Moxifloxacin should be used with caution in patients with a history of tendon damage from a quinolone antibiotic.⁽¹⁾ It should be discontinued immediately in any patient who develops tendinopathy or tendon rupture.⁽⁵⁾ Risk factors include; concurrent glucocorticoid use, >60 years, solid organ transplant, renal impairment, rheumatoid arthritis, hyperparathyroidism, musculoskeletal disorders, diabetes and strenuous physical activity.^(1, 5)Cases have been reported early in a treatment course to months after discontinuation of the antibiotic.⁽⁵⁾
- 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).⁽⁵⁾
- Moxifloxacin is associated with a risk of haemolytic anaemia in individuals with G6PD deficiency and should be avoided in these patients.
- 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, 5)
- Moxifloxacin is associated with an increased risk of peripheral neuropathy which may be irreversible. (1, 5)
- Moxifloxacin should be avoided in patients with myasthenia gravis as it may exacerbate the associated muscle weakness.^(1, 3, 4)
- 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⁾
- The IV formulation contains significant sodium content which is variable for different brands:
 - Each 400mg (250mL bag) of the Avelox® brand contains 34mmol of sodium.
 - Each 400mg (250mL bag) of the Moxifloxacin Kabi® brand contains 54.4mmol of sodium.⁽⁶⁾

FORMULATIONS

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

- 400mg tablet
- 400mg/250mL 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.

IV: ≥ 3 months to 18 years:

- 10mg/kg/dose (to a maximum of 400mg) once daily.⁽⁷⁾
- Moxifloxacin has good oral bioavailability (90%) consider switching to oral dosing as soon as clinically appropriate.^(3, 6)

Oral: ≥ 3 months to 18 years:

- Usual dose: 10mg/kg/dose (to a maximum of 400mg) once daily.⁽⁷⁾
- Multi-drug resistant tuberculosis: 10-15mg/kg/dose (to a maximum of 400mg) once daily.
- Doses should be rounded to the nearest portion of a tablet.

<u>Dosing in Overweight and Obese Children</u>: Minimal information available, dose on measured body weight.^(8, 9)

Renal impairment:

No dosage adjustments are required for patients with renal impairment. (3, 5)

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.^(3, 5)

ADMINISTRATION

IV infusion:

Administer undiluted over 60 minutes. (1, 5-7)

Oral:

- May be given without regard to food intake.^(3, 10)
- 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, 3, 5)
- 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. (10)
- Note: May be dispersed in water and mixed 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 may assist in masking the bitter taste. (10)

COMPATIBILITY (LIST IS NOT EXHAUSTIVE)

Compatible fluids:

- Glucose 5% and 10%
- Sodium chloride 0.9%

- Hartmann's
- Ringer's⁽⁶⁾

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).^(3, 7)
- ECG should be performed in patients with severe hepatic impairment and/or those on prolonged therapy. (4, 5, 7)
- Blood glucose should be monitored regularly in diabetic patients due to the risk of hyper or hypoglycaemia.⁽⁴⁾
- Patients should be instructed to report any joint or tendon pain, especially in those on prolonged courses.⁽⁵⁾

ADVERSE EFFECTS

Common: dizziness, injection site reactions, rash, itch, nausea, vomiting, diarrhoea, abdominal pain, dyspepsia,.^(1, 3)

Infrequent: prolongation of QT interval, ventricular tachyarrhythmias, palpitations, headache, insomnia, depression, restlessness, tremors, arthralgia, arthritis, tendonitis, raised liver function tests (LFTs), interstitial nephritis.^(1, 3)

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, 3)

STORAGE

- **Tablets:** Store below 25°C^(6, 11)
- **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. (6, 11)

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

- 1. Rossi S, editor. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2022.
- 2. Antibiotic Writing Group. Therapeutic Guidelines Antibiotic. West Melbourne: Therapeutic Guidelines Ltd; 2022. Available from: https://tgldcdp-tg-org-au.pklibresources.health.wa.gov.au/etgAccess.
- 3. Clinical Pharmacology [Internet]. Elsvier BV. 2022 [cited 18/07/2022]. Available from: http://www.clinicalpharmacology-ip.com.pklibresources.health.wa.gov.au/default.aspx.
- 4. IBM Micromedex [Internet]. Truven Health Analytics. 2022 [cited 18/07/2022]. Available from: http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/micromedex2/librarian.
- 5. Paediatric Drug information [Internet]. Lexicomp. 2022 [cited 13/07/2022].
- 6. Symons K. Ermer J. (editors). Australian injectable drugs handbook. Collingwood: The Society of Hospital Pharmacists of Australia; 2022.
- 7. 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; 2022.
- 8. Al-Dorzi HM, Al Harbi SA, Arabi YM. Antibiotic therapy of pneumonia in the obese patient: dosing and delivery. Curr Opin Infect Dis. 2014;27(2):165-73.
- 9. Kees MG, Weber S, Kees F, Horbach T. Pharmacokinetics of moxifloxacin in plasma and tissue of morbidly obese patients. J Antimicrob Chemother. 2011;66(10):2330-5.
- 10. Symons K, Emer J (editors). Australian Don't Rush to Crush Handboook. 4th edition ed. Collingwood: The Society of Hospital Pharmacists of Australia; 2021.
- 11. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2022. p. 1v. (various pagings).

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