MONOGRAPH

Metronidazole 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

Nitroimidazole antibiotic.[1-3]

INDICATIONS AND RESTRICTIONS

Metronidazole is active against anaerobic bacteria and some protozoa (e.g. giardia and trichomonas). It is also used in the treatment of *Clostridioides difficile* associated disease.[1, 3]

Oral: Unrestricted (green) antibiotic

This is not a restricted agent. Follow standard ChAMP guidelines where appropriate.

IV: Monitored (orange) antibiotic

Metronidazole is indicated for use as per the indications stipulated in Formulary One. For any other use, phone approval must be obtained from ChAMP before prescribing as per the Antimicrobial Stewardship Policy.

CONTRAINDICATIONS

- Hypersensitivity to metronidazole, tinidazole or any component of the formulation.[1, 2, 4, 5]

PRECAUTIONS

- Caution should be taken in any patient with a history of blood dyscrasias due to the risk of leucopenia – especially during extended treatment (>10 days) or high dose treatment.[1, 4] If leucopenia or abnormal neurological signs occur, discontinue metronidazole immediately.[4]
- Metronidazole is neurotoxic and may aggravate existing neurological diseases.[1] Monitor for peripheral and central neuropathy (such as paraesthesia, ataxia, dizziness, convulsive seizures) with prolonged courses and/or high doses of metronidazole (>10 days). [2]
- Alcohol (including ethanol, which may be contained in other liquid preparations of medications) should be avoided with metronidazole and for 24 hours after the last dose of metronidazole due to the risk of disulfiram-like reactions e.g. nausea, vomiting, headache, palpitations.[1, 2, 5]
- Avoid the use of metronidazole with fluorouracil due to the increased risk of fluorouracil toxicity.[1]
- Each 100 mL of the IV solution contains 13.5 mmol of sodium. [6]
- QT prolongation has been reported with metronidazole use. Use metronidazole with caution in patients with conditions that may increase the risk of QT prolongation.[4]
- Metronidazole and its metabolites may accumulate significantly in patients with severe renal impairment due to reduced urinary excretion. Avoid use or monitor closely for adverse effects.[1, 2]
- Reduce dose in severe liver impairment due to accumulation and monitor for adverse effects in those with all levels of liver impairment.[1, 2]

FORMULATIONS

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

- 40 mg/mL oral suspension
- 200 mg tablets
- 500 mg/100 mL solution for intravenous infusion

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Intravenous

Children ≥ 4 weeks:

- **Usual dose:** 12.5 mg/kg/dose (to maximum of 500 mg) 12 hourly.[2, 7]
- **Severe infections (including Clostridial or CNS infections):** 12.5 mg/kg/dose (to a maximum of 500 mg) 8 hourly[2, 7]
- **Surgical Prophylaxis (see individual surgical prophylaxis guidelines):** 12.5 mg/kg (to a maximum of 500 mg) as a single dose within 120 minutes prior to surgical incision.[3, 7]

Oral

Children ≥ 4 weeks:

- **Usual dose:** 10 mg/kg/dose (to a maximum of 400 mg) 12 hourly[1, 2, 7]
- **Severe infections:** 10 mg/kg/dose (to a maximum of 400 mg) 8 hourly[1, 2, 7]
- ***Clostridioides difficile* associated disease:** 10 mg/kg/dose (to a maximum of 400 mg) 8 hourly[1, 2, 7]
- **Amoebiasis:** 15 mg/kg/dose (to a maximum of 800 mg) 8 hourly.[1, 7] Follow with course of paromomycin.
- **Giardiasis:** 30 mg/kg/dose (to a maximum of 2000 mg) once daily for three days. Alternatively, use 10 mg/kg/dose (to a maximum of 400 mg) 8 hourly for five to seven days.[1, 7]

Renal impairment:

- eGFR calculator

Dose reduction is generally not required in cases of significant renal impairment. However, metabolites may accumulate in severe impairment possibly increasing the risk of adverse effects. Contact Pharmacy for advice.[2, 3, 5]

- For patients with a creatinine clearance less than 10 mL/minute, consider dosing at a maximum of 4 mg/kg/dose given 6 hourly.[5]

Hepatic impairment:

- In severe hepatic impairment (Child Pugh Class C), reduce the total daily dose to 50% as there may be accumulation of metronidazole and its metabolites.[2, 5, 8]
- Single doses for surgical prophylaxis do not require adjustment.[2]

ADMINISTRATION

IV Administration:

- Administer undiluted solution over 20 to 30 minutes at a maximum rate of 25 mg/minute. The solution may be further diluted to 1 in 5 or greater with a compatible fluid if necessary.[6]
- Metronidazole is incompatible with aluminium and must not be administered with equipment containing aluminium components (e.g. needles and cannula hubs).[2, 5, 6]

Oral Administration:

- Administer tablets with or soon after food to reduce stomach upset.[1, 2, 7]
- Administer oral liquid 1 hour before food to assist in absorption.[1, 7]
- Metronidazole has near 100% oral bioavailability – consider switching to oral dosing as soon as clinically appropriate. Good CNS levels are seen with oral administration.[4, 6]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Glucose 5%
- Sodium chloride 0.9%
- Glucose/sodium chloride solutions[6]

Note: Glucose 10% is not recommended due to the high osmolarity of the resulting solution.[6]

Compatible at Y-site:

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

MONITORING

- Monitor full blood picture (especially differential leucocyte count) and liver function weekly if treatment is to extend beyond 10 days.[1, 2, 5]
- Monitor for neurotoxic reactions (such as peripheral neuropathy, numbness, tingling, pain and/or weakness of the hands or feet) regularly.[1, 2, 5]

ADVERSE EFFECTS

Common: thrombophlebitis (with IV use), nausea, anorexia, abdominal pain, vomiting, dry mouth, diarrhoea, metallic taste, myalgia, CNS effects (e.g. dizziness, headache).[1, 8]

Infrequent: furry tongue, glossitis, stomatitis, paraesthesia.[1, 8]

Rare: peripheral neuropathy, pancreatitis, hepatitis, optic neuritis, thrombocytopenia, *Clostridioides difficile* associated disease, hypersensitivity reactions (e.g. rash, itch, flushing and fever), anaphylactic shock, angioedema, severe cutaneous adverse reactions, leucopenia, seizures and dark urine.[1, 8]

Leucopenia, peripheral neuropathy and central nervous system toxicity are more likely with high-dose and/or prolonged treatment and are all usually reversible.[1]

STORAGE

- **IV:** Store below 25°C (do not refrigerate) and protect from light. Exposure to normal room light during the administration process does not result in decomposition.[4, 6]
- **Suspension:** Store below 25°C and protect from light.[4]
- **Oral tablets:** Store below 30°C and protect from light.[4]

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 **metronidazole**. 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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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.
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File Path:	*W:\Safety & Quality\CAHS\CLOVERS MEDICAL Pharmacy\Procedures Protocols and Guidelines\ChAMP\Word\Monographs\PCH Templated (ED Guidelines)*		
Document Owner:	Head of Department – Infectious Diseases		
Reviewer / Team:	Children's Antimicrobial Management Program Pharmacist		
Date First Issued:	August 2013	Last Reviewed:	November 2024
Amendment Dates:	September 2021, October 2024	Next Review Date:	December 2027
Approved by:	Medication Safety Committee	Date:	December 2024
Endorsed by:	Chair, Drug and Therapeutics Committee	Date:	December 2024
Aboriginal Impact Statement and Declaration (ISD)		Date ISD approved:	31st August 2023
Standards Applicable:	NSQHS Standards:  NSMHS: N/A Child Safe Standards: N/A		

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