MONOGRAPH

Vancomycin (oral) 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

⚠ HIGH RISK MEDICINE ⚠

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring

DRUG CLASS

Glycopeptide antibacterial.[1, 2]

Oral vancomycin is a High Risk Medicine.

INDICATIONS AND RESTRICTIONS

- Oral administration of vancomycin is indicated in the treatment of severe or recurrent antibiotic-associated diarrhoea produced by *Clostridioides difficile*.[1, 3, 4]

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.

Oral vancomycin solution (25 mg/mL) is a **Special access scheme product**. SAS application(s) must be completed in accordance with the TGA regulations.

CONTRAINDICATIONS

- Hypersensitivity to vancomycin, teicoplanin or any component of the formulation.[2, 3, 5, 6]

PRECAUTIONS

Oral dosing must NEVER be used to treat a systemic infection.

- Oral absorption may be significantly increased in cases of inflammatory bowel conditions increasing the likelihood of adverse effects which may be worse in patients with renal impairment.[2, 3, 6, 7]
- Avoid concurrent use of anti-motility drugs and cease proton-pump inhibitors if possible.[6]

FORMULATIONS

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

- 125 mg oral capsules.
- 500 mg and 1 gram powder for reconstitution vial (multiple generic brands) – can be administered orally[4, 6, 8]
- 25 mg/mL for oral solution (SAS formulation) – only for use in outpatients who are not able to swallow the capsules and have a nasogastric tube.

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates and children less than 2 years of age:

C. difficile is not routinely treated in children less than 2 years of age as asymptomatic colonisation with toxigenic *C. difficile* is common, contact Infectious Diseases or Clinical Microbiology for advice.[9]

Child ≥ 2 years of age:

Treatment of Severe or recurrent *Clostridioides difficile*:

Oral:

- **Usual dose**: 10 mg/kg/dose (to a maximum of 125 mg) 6 hourly for 10 days.[1, 3, 6]
- **Life threatening or refractory infection**: The dose cap may be increased to 10 mg/kg/dose (to a maximum of 500 mg) 6 hourly for 10 days on discussion with Infectious Diseases or Clinical Microbiology.[5-8]

Tapering of the course may be recommended for the second or subsequent recurrence or ongoing refractory disease. If a tapering course is required, suggested dosing[4, 10]:

- 10 mg/kg/dose (to a maximum of 125 mg) 6 hourly for 14 days then
- 10 mg/kg/dose (to a maximum of 125 mg) 12 hourly for 7 days then
- 10 mg/kg/dose (to a maximum of 125 mg) once daily for 7 days then
- 10 mg/kg/dose (to a maximum of 125 mg) every second day for two to eight weeks.

Dosing in Overweight and Obese Children: Dose based on actual body weight.[3]

Renal impairment:

- As oral absorption of vancomycin is negligible, dose adjustment for oral administration is not required. [6, 7]
- Refer to the intravenous vancomycin monograph for dosage adjustments required for systemic use.

Hepatic impairment:

- As oral absorption of vancomycin is negligible, dose adjustment for oral administration is not required.[6]
- Refer to the intravenous vancomycin monograph for dosage adjustments required for systemic use.

RECONSTITUTION & ADMINISTRATION

- The oral capsules must be swallowed whole and cannot be opened. Oral vancomycin can be given with or without food.[8, 11]
- If capsules are unavailable, the patient has a nasogastric tube or is unable to swallow the capsules, the IV injection may be reconstituted and given orally.[3, 7]
    - Reconstitute as follows to give a 100 mg/mL solution:
        - 500 mg vial with 5 mL of water for injection
        - 1 g vial with 10 mL of water for injection.
    - This solution may be kept for an individual patient for **ORAL** use at between 2°C and 8°C for 24 hours.[12]
    - Flavouring syrups may be added to mask the taste.[4, 11]
    - An SAS solution is available for outpatients with nasogastric tubes to facilitate administration
- Oral solution (SAS) must be reconstituted with the supplied diluent as outlined in the product information prior to dispensing.

MONITORING

- Due to negligible absorption, monitoring of systemic vancomycin levels with oral administration is not required.[6-8]
- Consider serial auditory function monitoring in patients with underlying hearing loss or if concurrent therapy with other ototoxic medications is required.[5, 7]

ADVERSE EFFECTS

More severe adverse effects are generally only seen in cases of significant serum concentrations (e.g. in patients with renal impairment with severe inflammatory bowel disease).[3]

Common: indigestion, nausea, vomiting, diarrhoea, chills, fatigue, fever, headache, hypokalaemia, abdominal pain, urinary tract infection, and back pain.[2, 3, 6]

Infrequent: peripheral oedema, nephrotoxicity, constipation.[6]

Rare: interstitial nephritis, ototoxicity, renal failure or impairment, thrombocytopenia and vasculitis.[2, 3, 6]

STORAGE

- Capsules: store below 25°C and protect from moisture.[2]
- IV solution for oral administration: The reconstituted solution may be kept for an individual patient for **ORAL** use at between 2 and 8°C for 24 hours.[12]
- The SAS oral solution should be protected from light and stored between 2-8°C before and after reconstitution. The solution should be discarded 14 days after reconstitution.[6]

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 **oral vancomycin**. 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. 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.
2. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2022 [cited 2023 21st Mar].
3. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2023 [cited 2023 2nd May]. Available from: https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/.
4. 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.
5. IBM Micromedex [Internet]. Truven Health Analytics. 2023 [cited 2023 August 3rd]. Available from: http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/micromedex2/librarian.
6. Up To Date - Paediatric Drug information [Internet]. Lexicomp. 2023 [cited 2023 July 31st]. Available from: https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/table-of-contents/drug-information/pediatric-drug-information.

7. Paediatric Formulary Committee. BNF for Children: 2023. London: BMJ Group Pharmaceutical Press; 2023.
8. Clinical Pharmacology powered by ClinicalKey [Internet]. Elsvier. 2023 [cited 2023 August 3rd]. Available from: https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/.
9. *Clostridioides difficile* infection in children: Clinical features and diagnosis [Internet]. Up to Date. 2022 [cited 2023 August 3rd].
10. Trubiano JA, Cheng AC, Korman TM, Roder C, Campbell A, May MLA, et al. Australasian Society of Infectious Diseases updated guidelines for the management of Clostridium difficile infection in adults and children in Australia and New Zealand. Internal Medicine Journal. 2016;46(4):479-93.
11. Symons K, Emer J (editors). Australian Don't Rush to Crush Handboook. 4th edition ed. Collingwood: The Society of Hospital Pharmacists of Australia; 2021.
12. Symons K. Ermer J. (editors). Australian injectable drugs handbook. Collingwood: The Society of Hospital Pharmacists of Australia; 2022.

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