MONOGRAPH

VinORELBine

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

VinORELBine is a Vinca Alkaloid that interferes with microtubule assembly[1, 2]

VinORELBine is a High Risk Medicine.

VinORELBine is a Cytotoxic Medicine.

Extravasation: VinORELBine *is* a vesicant.[3] Refer to Extravasation of Antineoplastic (Cytotoxic) Agents Guideline.

Emetogenic Rating: Minimal unless combined with other chemotherapeutic agents. Refer to Anti-cancer Induced Nausea and Vomiting (AINV) Management Guideline.

INDICATIONS AND RESTRICTIONS

VinORELBinecan only be prescribed by Oncologists or Haematologists as per protocol for the treatment of malignancy.

CONTRAINDICATIONS

VinORELBine is fatal if given intrathecally.[1]

- Hypersensitivity to VinORELBine or any component of the formulation.[3]
- Drug induced severe granulocytopenia or severe thrombocytopenia.[3]

PRECAUTIONS [1, 2, 4]

- VinORELBine is a **cytotoxic** medication and must be handled with care. See Cytotoxic Biotherapy Agents Safety.
- Myocardial ischaemia and myocardial infarction have been reported rarely with vinca-alkaloids
- Previous (up to 2 weeks) or concurrent treatment with mitomycin can cause acute shortness of breath and severe bronchospasm.

FORMULATIONS

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

- VinORELBine: 50 mg/mL vial

DOSAGE & DOSAGE ADJUSTMENTS

Dosage as per treatment protocol in the OIMS (Oncology Information Management System).

Renal impairment:

- No dosage adjustment required

Hepatic impairment:

- Reduce doses according to bilirubin concentration in hepatic impairment.[2] Refer to treatment protocol.

Treatment related toxicity:

- Dose adjustment as per treatment protocol.

RECONSTITUTION & ADMINISTRATION

- Handle as cytotoxic

VinORELBine must be compounded by Pharmacy Compounding Services (PCS) in a cytotoxic drug safety cabinet by pharmacy personnel who have appropriate training and validation in aseptic and cytotoxic drug reconstitution and handling techniques.

- **IV infusion:**
  - Dilute dose in appropriate volume of sodium chloride 0.9%.
  - VinORELBine is to be compounded in a minibag (**NOT** a syringe) to prevent accidental intrathecal administration.[4] A warning label **"WARNING – For intravenous use ONLY.**

Fatal if given by any other route" must be attached to the IV minibag and outer bag of all VinORELBine products.[1, 5]

- Visually inspect parenteral products for particulate matter and discolouration.[4]

- **Administration:**
  - VinORELBine is for INTRAVENOUS (IV) use only. See Cytotoxic/Biotherapy Agents Administration.
  - VinORELBine is a vesicant, extravasation is a medical emergency and causes severe complications.[6] Stop the infusion and take immediate action if extravasation occurs, refer to Extravasation of Antineoplastic (Cytotoxic) Agents Guideline.[6]
  - To prevent extravasation; ensure proper catheter or needle positioning prior to administration.[3]
  - Administer by intravenous infusion via a mini-bag over 6 – 10 minutes or as per treatment protocol.[1, 3, 4, 6, 7] Longer infusions of 15 - 30 minutes may be administered via a side port of a free flowing IV line.[1, 3, 4, 6, 7] Longer infusions may increase the risk of pain and phlebitis.[1, 6, 7]

- **Post administration:** Flush with at least 40 mL (central line) or 75 mL (peripheral line) of sodium chloride 0.9% or glucose 5% as per the OIMS.[1, 2, 4]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids: Sodium chloride 0.9%, Sodium Chloride 0.45%, Glucose 5%, Hartmann's solution, Ringer's solution.[1, 6]

Compatible and INCOMPATIBLE drugs:

Antineoplastic therapies are not routinely administered with other medications. Consult two or more drugs references *(Compatibilities of IV drugs)* or pharmacy when there is a requirement for medications to be given concurrently.

MONITORING [1, 2, 3]

Pre-administration: Assess for ileus/constipation, abdominal pain, or any peripheral neuropathies (paraesthesia, hypesthesia, hyporeflexia and muscle weakness) including asymptomatic depression of Achilles reflex.

- Ensure patency of the line or vein before administration
- Extravasation and infusion site reactions
- Full blood picture with differential and platelet count
- Liver function tests
- Verify pregnancy status prior to treatment in patients who could become pregnant
- Pulmonary symptoms (worsening from baseline)
- Neurotoxicity

ADVERSE EFFECTS

Common: Peripheral neuropathy, nausea, vomiting, constipation, neutropenia, leukopenia, thrombocytopenia, anaemia, transaminitis , injection site reactions, weakness/lethargy. [1, 2, 3]

Infrequent: Diarrhoea, alopecia, increases in serum creatinine, phlebitis, chest pain, febrile neutropenia, serum bilirubin increase, sepsis, ototoxicity, Severe bone marrow suppression including neutropenia, anaemia and thrombocytopenia.[1, 2, 3]

Rare: Myocardial infarction[2]

STORAGE

- Vial: Store between 2 – 8 degrees Celsius. Do not freeze. Protect from light. [6]
- Compounded IV infusion: Store between 2-8 degrees Celsius. Protect from light.

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.

- VinORELBINE is a substrate of CYP3A4 (minor) and CYP2D6 (minor), inhibitors and inducers of these enzymes may increase/decrease concentrations of VinORELBINE.[1] Previous (up to 2 weeks) or current administration with Mitomycin may result in acute shortness of breath and bronchospasm.[1]
- Co administration with Cisplatin increases the risk of granulocytopenia.[1]

Please note: The information contained in this guideline is to assist with the preparation and administration of **VinORELBine**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Cytotoxic Biotherapy Agents Administration

Cytotoxic Biotherapy Agents Extravasation

Cytotoxic Biotherapy Agents Safety

Chemotherapy Induced Nausea and Vomiting Management

High Risk Medicine

Related external legislation, policies and guidelines

Mandatory Standard for Vinca Alkaloids

References

1. 2022. Children's Oncology Group. Commercial agent monograph. [cited January 2023]; 10.1:[241 - 2 pp.].
2. Australian Medicines Handbook Vinorelbine Australian Medicines Handbook Pty Ltd.

; 2022 September 2022].
3. UpToDate. Lexicomp 2022. Vinorelbine: Paediatric Drug Information October 2022.
4. Clinical Pharmacology. Elsevier Inc; 2022. Vinorelbine October 2022.
5. Institute for Safe Medication Practices 2020-2021. ISMP Targeted Medication Safety Best Practices for HospitalsOctober 2022]:[3 p.].
6. Australian Injectable Drugs Handbook, 8th Edition Vinorelbine - Antineoplastic SHPA 2022 December 2022].
7. 2022. Children's Oncology Group. Parental and Oral Chemotherapy Administration Guidelines.[cited January 2023]; 11:[76 p.].

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