MONOGRAPH

Nelarabine

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

DRUG CLASS

Antimetabolite (Purine analogue)[1]

Nelarabine is a High Risk Medicine.

Nelarabine is a Cytotoxic Medicine.

Extravasation: Nelarabine has no extravasation potential. Refer to Extravasation of Antineoplastic (Cytotoxic) Agents Policy.

Emetogenic Rating: Nelarabine has a minimal emetogenic risk. Refer to Chemotherapy Induced Nausea and Vomiting (CINV) Management Guideline.

INDICATIONS AND RESTRICTIONS

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

Special access scheme product. SAS application(s) must be completed in accordance to the TGA regulations.

CONTRAINDICATIONS

- Hypersensitivity to nelarabine or any component of the formulation.[1, 2]

PRECAUTIONS

- Severe neurologic adverse effects. [1, 2, 3]
- Patients previously or concurrently treated with intrathecal chemotherapy or craniospinal irradiation are potentially at increased risk for neurological adverse events.[1, 2]
- Concomitant use of live vaccines[1, 2, 3]

FORMULATIONS

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

- Nelarabine (SAS) 250 mg/50 mL (5 mg/mL) vial

DOSAGE & DOSAGE ADJUSTMENTS

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

Renal impairment:

- There are no dose adjustments provided by the manufacturer or treatment protocol; monitor closely.[1, 2]

Hepatic impairment:

- There are no dose adjustments provided by the manufacturer or treatment protocol; monitor closely.[1, 2, 4]

Treatment related toxicity:

- Dose adjustment as per treatment protocol.

ADMINISTRATION

- Handle as cytotoxic.
- Nelarabine must be compounded in a cytotoxic drug safety cabinet by pharmacy personnel who have appropriate training and validation in aseptic and cytotoxic drug reconstitution and handling techniques.
- The prescribed dose is added neat into an empty ethylene vinyl acetate (EVA) infusion bag.

Intravenous infusion:

- Administer over one hour or a per treatment protocol.[1, 2]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- No compatibility information is available.

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

- Neurotoxicity: monitor for signs of neurotoxicity which may present as altered mental states, severe somnolence, seizure, peripheral neuropathy, confusion, ataxia, paraesthesia, hypoesthesia, coma or craniospinal demyelenation.[1, 2, 3, 4, 5]Complete blood count [1, 2, 3, 5]
- Renal function[1, 2, 3, 5]
- Liver function[2, 3, 5]
- Tumour lysis syndrome[1, 2, 3, 5]

ADVERSE EFFECTS

Common (>20% of patients): nausea, diarrhea, vomiting, constipation, fatigue, fever, anaemia, decreased white blood cell count, decreased neutrophil count, decrease platelet count, decreased lymphocyte count, infection, cough, dyspnoea, dizziness.[4]

Infrequent (4-20% of patients): peripheral neuropathy, paraesthesia, hypoesthesia, headache, pain, abdominal distension, stomatitis, oedema, rigors, febrile neutropenia, sinus tachycardia, abnormal gait, myalgia, arthralgia, somnolence, confusion, insomnia, depression, impaired consciousness, pleural effusion, epistaxis, petechia, wheezing, increased transaminases, increased bilirubin, decreased albumin, increased creatinine, decreased calcium, decreased magnesium, decreased potassium, decreased or increased glucose, weakness, blurred vision, seizure. [4]

Rare (≤3% of patients): tumour lysis syndrome, demyelination and ascending peripheral neuropathies similar in appearance to Guillain-Barré syndrome, increased creatinine phosphokinase, fatal opportunistic infection, pneumothorax, progressive multifocal leukoencephalopathy, rhabdomyolysis, dysgeusia, ataxia, dysphagia, aphasia, amnesia.[4]

STORAGE

Unopened vial: store at room temperature.[3, 4]

Opened vial, glass container or PVC IV infusion bag: stable for up to 8 hours at 30°C.[1, 3, 4]

Ethylene Vinyl Acetate (EVA) IV infusion bag: stable for up to 7 days. Refrigerate at 2-8° C. Protect from light.[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 **Nelarabine**. 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

PCH SAS Application Online Information Hub

References

1. Novartis Pharmaceuticals. Atriance: Product Information. 2009 [cited 12th January 2023]. Available from: https://www.ema.europa.eu/en/documents/product-information/atriance-epar-product-information_en.pdf.
2. UpToDate. Nelarabine: Drug information. 2023 [cited 12th January 2023]. Available from: https://www-uptodate-com.
3. Micromedex. Nelarabine: in-depth answers. 2023 [cited 12th January 2023]. Available from: www.micromedexsolutions.com.
4. Children's Oncology Group.

Drug Information for Commercial Agents used by the Children's Oncology Group 2022 [cited 18th August 2022]. Available from: https://www.cogmembers.org/_files/disc/Pharmacy/CommercialAgentsMonographs.pdf.
5. Children's Oncology Group. Parenteral and Oral Chemotherapy Administration Guidelines used by the Children's Oncology Group 2022 [cited 4th October 2022]; Vol. 10.1. Available from: https://www.cogmembers.org/_files/disc/Pharmacy/ChemoAdminGuidelines.pdf.
6. Stabilis 4.0. Nelarabine. 2023 [cited 10th February 2023]. Available from: https://www.stabilis.org/.

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