Paediatric Medication Guideline

Use of recombinant factor VIII (8) concentrates in Haemophilia A

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Version No.	V1.0		
Risk Rating	Very high		
Primary Document			
Custodian	Director of Haematology	**Approval date**	21/11/2024
Accountable Officer	Executive Director Clinical Services	**Effective date**	22/11/2024
Applicable to	All clinical staff prescribing and administering recombinant factor VII (8)	**Review date**	21/11/2025

HUMAN RIGHTS

This governance document has been human rights compatibility assessed. No limitations were identified indicating reasonable confidence that, when adhered to, there are no implications arising under the *Human Rights Act 2019.*

PURPOSE

The purpose of this guideline is to provide clinical advice around the use of recombinant factor VIII (8) in paediatric patients under the care of Queensland Children's Hospital (QCH).

SCOPE

This guideline is intended to assist all clinical staff to prescribe and administer recombinant factor VIII (8) appropriately to patients at QCH. It is not intended to be a substitute for specific professional or clinical advice, or to replace consultation with senior staff, which should always be sought if clinically relevant.

This material is published by Queensland Health with the intention of providing a guideline for use in paediatric patients under the care of/as recommended by Children's Health Queensland (CHQ). Anyone wishing to use this guideline outside CHQ should refer to their local Medicines Committee before using.

GUIDELINE

DESCRIPTION AND INDICATIONS FOR USE

1. Use of recombinant factor products

- Used for the prevention and control of bleeding episodes in people with Haemophilia A.
- Administered on demand in the event of bleeding, injury, and/or surgical management pre and post-operatively.
- Can be used for prophylaxis in severe and moderate Haemophilia A to prevent bleeds.

PRESCRIBING INSTRUCTIONS

X	**Contraindications** • In patients who have manifested severe hypersensitivity reactions, including anaphylaxis to the product or any of its components. Severe hypersensitivity reactions were not observed in clinical trials; however, these have been known to occur with use of other factor VIII (8) replacement factors. • Anaphylactic reactions include: • Swelling or lips, tongue, and airway • Rashes or hives • Shortness of breath, wheezing or difficulty breathing • Chest pain or discomfort
!	**Precautions** • Adverse drug reactions include arthralgia, malaise, headache and rash. • Neutralising antibody (inhibitor) development.

DOSE

ALERT

Factor VIII (8) doses are always rounded up to the nearest vial size(s) and ideally should never be discarded.

Individual dosing plan as per the Haemophilia team.

Factor VIII (8) doses for patients living with haemophilia A are calculated based on the severity of the patients' factor deficiency, the patients' body weight, the location of bleed, extent of bleeding and the patients' clinical condition.
Recombinant factor doses are prescribed in International Units (IU).
These dosing guidelines can be found in the Guidelines for the Management of Haemophilia in Australia
HaemophiliaGuidelines-interactive-updated-260317v2.pdf (blood.gov.au)

In the absence of a factor VIII (8) inhibitor please dose as follows:
Each international unit (IU) of factor VIII (8) per kilogram (kg) of body weight infused intravenously will raise the plasma factor VIII (8) level by about 2 IU/dl.

Example: 50 IU/kg of factor VIII concentrate gives approximately 100% rise in plasma factor VIII (8) levels.

ADMINISTRATION INSTRUCTIONS

ALERT
Eloctate® is not a blood product!
Eloctate® is stored and supplied by pharmacy at QCH, not Blood Bank!

Eloctate® is an Extended Half-Life (EHL) recombinant (synthetic) factor VIII (8) replacement product used to treat and prevent bleeding in children with Haemophilia A.

Eloctate® is formulated as a sterile, non-pyrogenic, preservative-free, lyophilised white powder for intravenous (IV) administration in a single-use vial.

Vial sizes: 250, 500, 1000 & 2000 international units (IU).

3000 IU vials are not stocked in pharmacy and are ONLY available by direct order from the supplier.

Store all non-reconstituted vials in the ward medication fridge (2-8ºC) after delivery/collection from pharmacy.

Non-reconstituted vials are stable both refrigerated or at room temperature (25ºC).

Figure 1: Available Eloctate vial sizes

RECONSTITUTION/DILUTION

Follow the manufacturers reconstitution guidelines included inside each box of factor concentrate.

The reconstitution guidelines can also be found online:

elo_eloctateinstructions_for_use.pdf

DO NOT use Eloctate® if the product has been opened or if the diluent provided is not clear.

Only use the reconstituted solution if slightly opalescent and colourless.

Following reconstitution of Eloctate® the product can be stored at room temperature (up to 30ºC) for 6 hours.

If the reconstituted product is not used within the 6 hours, it must be discarded. Please do not return reconstituted factor to the refrigerator.

Further dilution prior to administration is not required.

ROUTE AND METHOD OF ADMINISTRATION

It is the nursing staff's responsibility to administer medications in accordance with the CHQ Medication Policy: CHQ Medication – administration policy.

Eloctate® is administered via a **slow intravenous bolus (2 minutes).** Australian Injectable Drugs Handbook-Eloctate

Eloctate® medication is compatible with sodium chloride 0.9%. **DO NOT** use the provided pre-filled glass diluent syringe on any central venous access device. Please draw up medication with a 10mL luer lock sterile syringe.

The diluent syringe is only designed for use when accessing a peripheral vein if compatible with the needless access device. If multiple vials used for a dose, then draw up into a 10mL or appropriately sized syringe.

ALERT

Ensure that you have the correct factor product and vial size before reconstituting. Please note Eloctate® and Alprolix® vials are the same colour and the packaging is almost identical and stored together in fridge.

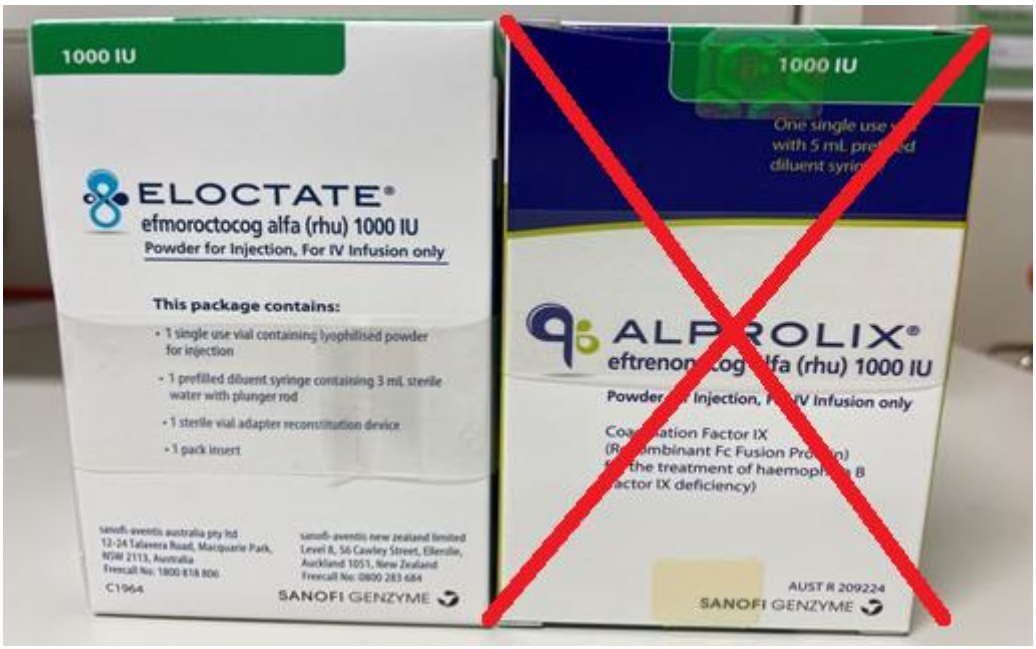

Figure 2: Eloctate® packaging (note similar packaging to Alprolix®)

CLINICAL CONSIDERATIONS

ADVERSE REACTIONS

Allergic reactions may occur with Eloctate®.

Your body can also make antibodies called "inhibitors" against the Eloctate® which may stop this working properly.

Common side effects include headaches, rashes, joint pain or general discomfort.

MONITORING

There are no known drug interactions with Eloctate®.

Adverse effects are rarely observed in patients receiving Eloctate® but health providers should always monitor for allergic reactions, especially if the patient is receiving the product for the first time.

Standard intravenous infusion monitoring (site, lines) and observations (Blood product observations NOT required).

THERAPEUTIC DRUG MONITORING

Factor VIII (8) levels are not always required with every dose of medication.

If drug monitoring (factor levels) is required, this will be indicated by the haemophilia team.

ADDITIONAL INFORMATION

All unused factor products should be returned to pharmacy on discharge.

SUPPORTING DOCUMENTS

Standards:

- Australian Standard Medical and Surgical Equipment
- National Safety and Quality Health Service (NSQHS) Standards

Supporting documents:

- CHQ-PROC-01039 – Medication – Administration
- CHQ-PROC-19007 – Medication Refrigerator Temperature Monitoring
- The Guidelines for Management of Haemophilia in Australia HaemophiliaGuidelines-interactive-updated-260317v2.pdf (blood.gov.au)
- National Blood Authority Australia

CONSULTATION

Key stakeholders who reviewed this version:

• Nurse Practitioner Haemophilia • SMO/ Director of Haemophilia • Clinical Nurse(s) Haemophilia / Haematology • QPPHON Educator	• Director of Haematology/ Haemophilia Services • Haematologists • MAC 17/10/2024

DEFINITIONS

Term	Definition
Factor VIII	Factor 8 clotting protein
Eloctate®	Recombinant factor eight concentrate

GUIDELINE REVISION AND APPROVAL HISTORY

Version No.	Modified by	Amendments authorised by	Approved by	Comments
1.0	Clinical Nurse(s) Haemophilia / Haematology	Haematology Director	Executive Director Clinical Services	Endorsed by CHQ MAC 17/10/2024

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Accreditation references	The National Safety and Quality Health Service (NSQHS) Standards (1-8): • Standard 4: Medication Safety