ENOXAPARIN

Read in conjunction with Disclaimer

⚠ HIGH RISK Medication ⚠

Formulary: Highly Restricted Requires neonatologist or haematologist approval before commencing.	
Presentation	**Prefilled syringe:** 20 mg/0.2 mL – proprietry product must be diluted prior to administration.
Classification	Low molecular weight heparin.
Indication	Prevention and treatment of thromboembolic disorders.
Contraindications	• Active uncontrollable bleeding. • Severe thrombocytopenia. • Evidence of intracranial or GI bleeding. • Acute bacterial endocarditis. • History of heparin induced thrombocytopenia (HIT) or hypersensitivity to heparins.
Precautions	• Use with caution in patients with conditions that increase the risk of bleeding. • Therapeutic hypothermia: not the preferred anticoagulant. • **Lumbar puncture and other surgical procedures:** Epidural haematoma has been reported in paediatric patients who underwent lumbar puncture while receiving enoxaparin. It is recommended that 2 doses of enoxaparin be withheld prior to lumbar puncture or any invasive surgical procedure. It may be recommended to obtain Anti Factor Xa levels prior to high-risk procedures. Consult haematology for further advice.
Monitoring	• Monitor platelet count every 2 to 3 days. • Monitor potassium levels. • Renal function. **Anti Factor Xa peak level monitoring for treatment of thromboembolic disorders:** • When treating thromboses, maintain a peak Anti Factor Xa level of 0.5 to 1 units/mL. • Take the first peak Anti Factor Xa level **4 hours** (no later than 6 hours) **after the fourth dose** and refer to the Anti Factor Xa Level Dose Adjustment table for recommendations. • The timing of Anti Factor Xa level monitoring is very important for accurate interpretation of results. If levels are delayed longer than 6 hours after a dose contact haematology for advise on when to take the next level. • If possible, at KEMH levels are best taken during business hours to allow for prompt delivery for off-site processing.
Compatibility	**Fluids:** Sodium chloride 0.9%, glucose 5%
Interactions	• Administration with other medication that can affect the clotting process may increase the risk of bleeding; monitor closely. • Heparins can cause hyperkalaemia; combination with other medications that can increase potassium concentration will increase this risk; monitor potassium concentration.

Side Effects	Bleeding, bruising and pain at injection site, elevated liver enzymes, anaemia, diarrhoea, peripheral oedema, fever, allergic reaction, urticaria, hyperkalaemia.
	Rare: Thrombocytopenia, cholestasis, bullous dermatitis, osteoporosis (long term use).
Storage & Stability	**Prefilled syringe:** Store at room temperature, below 25ºC.

SUBCUTANEOUS INJECTION

Presentation

Prefilled syringe: 20 mg/0.2 mL – proprietry product must be diluted prior to administration, see Preparation.
Available from CIVAS: *10 mg/mL (PCH and KEMH), 20 mg/mL (KEMH only), 40 mg/mL (PCH only).*

Dosage

Prophylaxis – Starting dose

Postnatal age (months)	Dose	Frequency
0 to 2 months	0.75 mg/kg/dose	Every 12 hours
More than 2 months	0.5 mg/kg/dose	Every 12 hours

Treatment – Starting dose

Postnatal age (months)	Dose	Frequency
0 to 2 months	1.5 mg/kg/dose	Every 12 hours
More than 2 months	1 mg/kg/dose	Every 12 hours

Note: Some references suggest the need for higher starting doses of 1.7 mg/kg for term neonates and 2 mg/kg/dose for preterm neonates. Consult haematology.

Dose Adjustment:

- **See Anti Factor Xa Level Dose Adjustment section below**
- **Renal Impairment:** There are no neonatal or pediatric specific recommendations; use with caution and monitor patient closely; based on experience in adult patients, dosage adjustment may be required.

Preparation

10 mg/mL for small doses less than 2 mg
Dilution:

- Draw up 1.8 mL of compatible fluid into an appropriate syringe.
- Inject the entire contents of one enoxaparin 20 mg/0.2 mL prefilled syringe into the syringe containing the diluent to make a final volume of 2 mL.
- *Concentration now equal to* **10 mg/mL.**

20 mg/mL for doses 2 mg and higher
Dilution:

- Draw up 0.8 mL of compatible fluid into an appropriate syringe.
- Inject the entire contents of one enoxaparin 20 mg/0.2 mL prefilled syringe into the syringe containing the diluent to make a final volume of 1 mL.
- *Concentration now equal to* **20 mg/mL.**

Administration

See next page.

Administration	• Draw up the prescribed dose of the diluted solution. • Inject into the **subcutaneous tissue** as per the Medication Administration Guideline. • May be administered via an Insuflon™ Subcutaneous Device. • Discard any unused fluid immediately.

Anti Factor Xa Level Dose Adjustment

Anti Factor Xa	Dose Adjustment	Time to Repeat Anti Factor Xa Level
Less than 0.35 units/mL	Increase dose by 25%	4 hours after second adjusted dose.
0.35 to 0.49 units/mL	Increase dose by 10%	4 hours after second adjusted dose.
0.5 to 1 unit/mL	Keep same dose	The next day, then 1 week later, then every 1 to 4 weeks or as directed by haematologist (4 hours after dose).
1.1 to 1.5 units/mL	Decrease dose by 20%	• Consider checking trough level before next dose to confirm drug clearance. • Then take peak level 4 hours after second adjusted dose.
1.6 to 2 units/mL	Delay next dose by 3 hours and decrease dose by 30%	• Consider checking trough level before next dose to confirm drug clearance. • Then take peak level 4 hours after second adjusted dose.
Greater than 2 units/mL	Hold all doses until Anti Factor Xa is 0.5 units/mL, then decrease dose by 40%	• While level is greater than 0.5 units/mL: 12 hours after last dose and every 12 hours until Anti Factor Xa less than 0.5 units/mL. • Once enoxaparin restarted: 4 hours after second dose; may consider more frequent monitoring based on clinical scenario.

Protamine for Reversal

Protamine has been shown to only partially reverse the action of enoxaparin.

If protamine sulfate is given within 3 to 4 hours of the last enoxaparin the recommended dose is **1 mg protamine sulfate per 1 mg enoxaparin** (Maximum dose of 50 mg). There is no information available for paediatric dosing outside of this time frame.

Protamine is available as a 50 mg/5 mL (10 mg/mL) ampoule. Administer protamine as a 10 mg/mL (undiluted) intravenous infusion not exceeding 5 mg/min.

Hypersensitivity reactions to protamine sulfate may occur in patients with known hypersensitivity reactions to fish or those previously exposed to protamine therapy or protamine-containing insulin.

Related Policies, Procedures, and Guidelines

HDWA Mandatory Policies:

MP 0131/20: WA High Risk Medication Policy

Clinical Practice Guidelines:

CAHS Neonatology Thromboembolic Disorders Guideline

Pharmaceutical and Medicines Management Guidelines:

CAHS Neonatology – Medication Administration Guideline

High Risk Medicines

References

Australasian Neonatal Medicines Formulary (ANMF). Enoxaparin. In: Australasian Neonatal Medicines Formulary [Internet]. Sydney, New South Wales; 2021 [cited 2025 Jan 09]. Available from: www.anmfonline.org

Malowany JI, Monagle P, Knoppert DC, et al. Enoxaparin for neonatal thrombosis: a call for higher dose for neonates. Thromb Res 2008;122(6):826–30.

Monagle P, Chan AKC, Goldenberg NA, Ichord RN, Journeycake JM, Nowak-Göttl U, Vesely SK. Antithrombotic therapy in neonates and children: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (9th Edition). Chest. 2012;141(2 Suppl):e737S-e801S. doi: 10.1378/chest.11-2308.

Monagle P, Michelson AD, Bovill E, Andrew M. Antithrombotic therapy in children. Chest. 2001;119(1):344S-70S.

Micromedex Solutions. Enoxaparin. In: Neofax [Internet]. Greenwood Village (CO): IBM Watson Health; 2023 [cited 2025 Jan 09]. Available from: http://neofax.micromedexsolutions.com/neofax

UpToDate Lexidrug. Enoxaparin (including biosimilars available in Canada): Pediatric drug information. In: UpToDate Lexidrug [Internet]. Wolters Kluwer; 2025. [cited 2025 Jan 07]. Available from: www.uptodate.com

Document history

<table>
<tr><td>Keywords</td><td colspan="5">Enoxaparin, Clexane, LMWH, low molecular weight heparin, heparin</td></tr>
<tr><td>Document Owner:</td><td colspan="5">Chief Pharmacist</td></tr>
<tr><td>Author/ Reviewer</td><td colspan="5">KEMH & PCH Pharmacy/Neonatology Directorate</td></tr>
<tr><td>Version Info:</td><td colspan="5">V1.0</td></tr>
<tr><td>Date First Issued:</td><td>09/01/2025</td><td>Last Reviewed:</td><td>N/A</td><td>Review Date:</td><td>09/01/2030</td></tr>
<tr><td>Endorsed by:</td><td colspan="3">Neonatal Directorate Management Group</td><td>Date:</td><td>25/03/2025</td></tr>
<tr><td rowspan="2">NSQHS Standards Applicable:</td><td colspan="3">☒ Std 1: Clinical Governance</td><td colspan="2">☒ Std 4: Medication Safety</td></tr>
<tr><td colspan="3">☒ Std 7: Blood Management</td><td colspan="2"></td></tr>
<tr><td colspan="6">Printed or personally saved electronic copies of this document are considered uncontrolled.
Access the current version from WNHS HealthPoint.</td></tr>
</table>

This document can be made available in alternative formats on request for a person with a disability.