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## **NOTICE: UNFRACTIONATED HEPARIN STOCK CONSTRAINTS**

The Adult Hospital Level and Paediatric Hospital Level Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) currently recommend the use of unfractionated heparin (UFH) injection for various indications.

Fresenius Kabi SA (Pty) Ltd is currently contracted to supply heparin 5000 IU/5ml and 25000 IU/5ml injections, in South Africa as a sole supplier. Fresenius Kabi has however, received an enforcement action letter from the South African Health Products Regulatory Authority (SAHPRA) to cease all manufacturing of heparin injection. This halt in production is likely to lead to stock constraints over the coming months.

Based on communication from Fresenius Kabi, available supplies are likely to be depleted within 4 to 5 months based on current demand. As there is currently no confirmation on when Fresenius Kabi will be allowed to re-commence manufacture of heparin injection, available supplies should be reserved for cases where therapeutic alternatives are not an option.

Facilities are advised to closely monitor available unfractionated heparin (UFH) stock levels and reserve supplies for specific populations in whom alternatives, such as Direct Oral Anticoagulants (DOACs, e.g., rivaroxaban) or Low Molecular Weight Heparins (LMWHs, e.g., enoxaparin, might not), may be unsuitable or contraindicated.

**Reserve the UFH for the following populations:**

- **Pregnant women with heart disease or mechanical prosthetic valves**, particularly where LMWH cannot be used due to the unavailability of access to Antifactor Xa monitoring.
- **Patients with severe renal impairment or on haemodialysis**, where anticoagulant choice should be guided by specialist consultation.

**Note:** Rivaroxaban is currently the preferred anticoagulant for venous thromboembolism (VTE) prophylaxis in medically ill inpatients, and for short-term (<6 months) VTE treatment.

Rivaroxaban prescribing guidance is included in the Adult Hospital Level Chapter 2: Blood and Blood Forming Organs. Please find the link to the Adult and Paediatric Hospital Level STGs and EML below:  
<https://www.health.gov.za/nhi-edp-stgs-eml/>

For indications where UFH is listed in the Adult and Paediatric STGs, see tables below for current STG recommendations and alternatives.

### Adult Hospital Level STGs and EML

Indication: Hospital Level (ADULTS)	Current Recommendations	Therapeutic Alternative Where No UFH is available
<b>Thromboembolism Prevention/Prophylaxis</b>  2.1.6 Anaemia, Sickle Cell 8.6.2 Diabetic Ketoacidosis (DKA) and Hyperosmolar Hyper glycaemic state (HHS) 9.4.2 Coronavirus Disease – 19 (COVID-19) 23.5.1 Haematological support – Thromboprophylaxis	To prevent venous thromboembolism: • Low molecular weight heparin (LMWH), e.g.: • Enoxaparin, SC, 40 mg daily. <b>OR</b> • Unfractionated heparin, SC, 5 000 units 12 hourly.	• Low molecular weight heparin (LMWH)B, e.g.: • Enoxaparin, SC, 40 mg daily.  <i>» In morbid obesity, dosing of LMWH should be individualised, in discussion with a specialist.</i> <i>» Renal impairment (eGFR &lt;30 mL/min): adjust dose to 20 mg daily.</i>
<b>Thromboembolism Prevention/Prophylaxis</b>  2.8.1 Venous Thromboembolism – Prophylaxis	<i>» For patients hospitalised due to medical illnesses at high risk of VTE:</i> • Rivaroxaban, oral, 10 mg daily while hospitalised. <b>For patients hospitalised due to medical illnesses and in whom rivaroxaban is contraindicated (see summary table below):</b> <i>» • Low molecular weight heparin, e.g.:</i> <i>» • Enoxaparin, SC, 40 mg daily.</i> <ul style="list-style-type: none"> <li><i>○ In morbid obesity, dosing of LMWH should be individualised, in discussion with a specialist.</i></li> <li><i>○ Renal impairment (eGFR &lt;30 mL/min): adjust dose to 20 mg daily.</i></li> </ul> <b>OR</b> • Unfractionated heparin, SC, 5 000 units 12 hourly. <ul style="list-style-type: none"> <li><i>○ Dose adjustment is generally not required for renal impairment.</i></li> <li><i>○ Monitor for bleeding complications.</i></li> </ul>	<b>For patients hospitalised due to medical illnesses at high risk of VTE:</b> • Rivaroxaban, oral, 10 mg daily while hospitalised. <b>For patients hospitalised due to medical illnesses and in whom rivaroxaban is contraindicated (see summary table below):</b> • Low molecular weight heparin, e.g.: • Enoxaparin, SC, 40 mg daily. <ul style="list-style-type: none"> <li><i>○ In morbid obesity, dosing of LMWH should be individualised, in discussion with a specialist.</i></li> <li><i>○ Renal impairment (eGFR &lt;30 mL/min): adjust dose to 20 mg daily.</i></li> </ul>
<b>2.8.2 Venous Thromboembolism – Acute Treatment</b>	<b>For proximal deep venous thrombosis and/or pulmonary embolism:</b> • Rivaroxaban, oral, 15 mg twice daily for 3 weeks, followed by 20 mg once daily for 3 months.  <b>If i) rivaroxaban is contraindicated, or ii) patient is high risk and requires long term anticoagulation (&gt; 6 months), e.g. recurrent VTE:</b> <i>» Start unfractionated or low molecular weight heparin simultaneously with warfarin.</i> <i>» After 5 days, heparin may be stopped if an INR within therapeutic range (INR between 2 and 3) has been reached and maintained for at least 24 hours.</i>	<b>For proximal deep venous thrombosis and/or pulmonary embolism:</b> • Rivaroxaban, oral, 15 mg twice daily for 3 weeks, followed by 20 mg once daily for 3 months.  <b>If i) rivaroxaban is contraindicated, or ii) patient is high risk and requires long term anticoagulation (&gt; 6 months), e.g. recurrent VTE:</b> <i>» Start low molecular weight heparin simultaneously with warfarin.</i> • Low molecular weight heparin, e.g.: • Enoxaparin, SC, 1.5 mg/kg daily,



Indication: Hospital Level (ADULTS)	Current Recommendations	Therapeutic Alternative Where No UFH is available
	<p><b>Note:</b> Heparin and warfarin therapy should overlap for at least 5 days.</p> <ul style="list-style-type: none"> <li>• Low molecular weight heparin, e.g.:</li> <li>• Enoxaparin, SC, 1.5 mg/kg daily,</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Enoxaparin, SC, 1 mg/kg 12 hourly.</li> </ul>	<p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Enoxaparin, SC, 1 mg/kg 12 hourly.</li> </ul>
<b>3.2.2 Non-ST Elevation Myocardial Infarction (NSTEMI) and Unstable Angina (UA)</b>	<p><b>For NSTEMI and UA (also for STEMI not given thrombolytic therapy):</b></p> <ul style="list-style-type: none"> <li>• Enoxaparin, SC, 1 mg/kg 12 hourly for minimum of 2 days.</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Unfractionated heparin, IV bolus, 5 000 units.               <ul style="list-style-type: none"> <li>◦ Follow with 1 000–1 200 units hourly monitored by aPTT.</li> <li>◦ Continue infusion for minimum of 2 days.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Enoxaparin, SC, 1 mg/kg 12 hourly for minimum of 2 days.</li> </ul>
<b>6.3 Heart Disease in Pregnancy Thromboprophylaxis</b>	<p><b>Thromboprophylaxis for pregnant women with valvular disease and atrial fibrillation:</b></p> <p><b>First trimester</b></p> <ul style="list-style-type: none"> <li>• Enoxaparin SC, 1 mg/kg 12 hourly.</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Unfractionated heparin, IV, 5 000 units as a bolus.               <ul style="list-style-type: none"> <li>◦ Followed by 1 000–1 200 units/hour as an infusion.</li> </ul> </li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Unfractionated heparin, SC, 15 000 units 12 hourly.               <ul style="list-style-type: none"> <li>◦ Adjust the dose to achieve a mid-target PTT at 2–3 x control.</li> </ul> </li> </ul> <p><b>After 36 weeks until delivery</b></p> <ul style="list-style-type: none"> <li>• Enoxaparin SC, 1 mg/kg 12 hourly.</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Unfractionated heparin, IV, 5 000 units as a bolus.               <ul style="list-style-type: none"> <li>◦ Followed by 1 000–1 200 units/hour as an infusion.</li> </ul> </li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Unfractionated heparin, SC, 15 000 units 12 hourly.               <ul style="list-style-type: none"> <li>◦ Adjust dose to keep aPTT 2–3 x control.</li> </ul> </li> </ul>	<p><b>Thromboprophylaxis for pregnant women with valvular disease and atrial fibrillation:</b></p> <p><b>First trimester</b></p> <ul style="list-style-type: none"> <li>• Enoxaparin SC, 1 mg/kg 12 hourly.</li> </ul> <p><b>After 36 weeks until delivery</b></p> <ul style="list-style-type: none"> <li>• Enoxaparin SC, 1 mg/kg 12 hourly.</li> </ul>
<b>23.4.1 Kidney Replacement Therapy (KRT) To reduce circuit hypercoagulability</b>	<ul style="list-style-type: none"> <li>• Unfractionated Heparin, 5000 units diluted in 50ml 0.9% sodium chloride (100 units/ml), administered directly into the RRT circuit.               <ul style="list-style-type: none"> <li>◦ Initial bolus: 10 to 20 units/kg.</li> <li>◦ Continue running infusion at 5 to 10 units/kg/hour.</li> <li>◦ Monitor using daily Activated Partial Thromboplastin Time (aPTT).</li> <li>◦ Maintain aPTT between 45 to 55 seconds.</li> </ul> </li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Enoxaparin, SC, 40mg daily</li> </ul> <p><i>Note: Only use heparin if there is no bleeding risk. Use saline flushes if there is a significant risk of bleeding.</i></p>	<ul style="list-style-type: none"> <li>• Enoxaparin, SC, 40mg daily</li> </ul> <p><i>Note: Only use heparin if there is no bleeding risk. Use saline flushes if there is a significant risk of bleeding.</i></p>

**Important Cautions:**

- » In morbid obesity dosing of LMWH should be individualised, in discussion with a specialist.
- » In renal failure (eGFR <30 mL/minute), the recommended prophylactic dose of enoxaparin is 20 mg daily and the recommended treatment dose is enoxaparin 1 mg/kg daily.
- » Pregnant women with mechanical prosthetic valves should not receive LMWH unless Antifactor Xa levels can be monitored reliably weekly. Therapeutic range is pre-dosing level of 0.6 units/mL and a 4-hour peak level of 1–1.2 units/mL.

**Paediatric Hospital Level STGs and EML**

Indication: Hospital Level (PAEDIATRICS)	Current Recommendations	Therapeutic Alternatives Where No UFH Is Available
<b>3.12 Venous Thrombo-embolic Disease</b> For acute thrombotic episode	<ul style="list-style-type: none"> <li>▪ Low molecular weight heparin (LMWH), e.g.               <ul style="list-style-type: none"> <li>• Enoxaparin sodium, SC, 1 mg/kg 12 hourly.</li> </ul> </li> <li><b>OR</b></li> <li>• Unfractionated heparin (UFH), IV, administered over 10 minutes as a bolus followed by an initial maintenance dose as a continuous infusion.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Low molecular weight heparin (LMWH), e.g.               <ul style="list-style-type: none"> <li>• Enoxaparin sodium, SC, 1 mg/kg 12 hourly.</li> </ul> </li> </ul>
<b>23.9.1 Thromboprophylaxis in ICU</b>  All children with at least one organ failure and central venous access likely require pharmacological prophylaxis against venous thrombo-embolism.	<ul style="list-style-type: none"> <li>▪ Low molecular weight heparin (LMWH), e.g.               <ul style="list-style-type: none"> <li>• Enoxaparin                   <ul style="list-style-type: none"> <li>» &lt; 2 months of age: 0.75 mg/kg/dose, SC, 12 hourly.</li> <li>» &gt; 2 months of age: 0.5 mg/kg/dose, SC, 12 hourly.</li> </ul> </li> </ul> </li> <li><i>Avoid with renal insufficiency. Monitoring: 0.2–0.4 anti-Xa U/mL (sample must be drawn in a nonheparinised syringe, 3–4 hours post dose).</i></li> <li><b>OR</b></li> <li>• Unfractionated heparin (UFH).               <ul style="list-style-type: none"> <li>» 10 units/kg/hour, IV, as a continuous infusion.</li> </ul> </li> <li><i>Not for routine use. Can be used in children with renal insufficiency, those requiring surgery or if they have a high risk of bleeding.</i></li> </ul>	<ul style="list-style-type: none"> <li>▪ Low molecular weight heparin (LMWH), e.g.               <ul style="list-style-type: none"> <li>• Enoxaparin                   <ul style="list-style-type: none"> <li>» &lt; 2 months of age: 0.75 mg/kg/dose, SC, 12 hourly.</li> <li>» &gt; 2 months of age: 0.5 mg/kg/dose, SC, 12 hourly.</li> </ul> </li> </ul> </li> <li><i>Avoid with renal insufficiency. Monitoring: 0.2–0.4 anti-Xa U/mL (sample must be drawn in a nonheparinised syringe, 3–4 hours post dose).</i></li> </ul>
<b>23.9.2 Treatment of VTE</b>	<ul style="list-style-type: none"> <li>▪ Low molecular weight heparin (LMWH), e.g.               <ul style="list-style-type: none"> <li>• Enoxaparin                   <ul style="list-style-type: none"> <li>» &lt; 2 months of age: 1.5 mg/kg/dose, SC, 12 hourly.</li> <li>» &gt; 2 months of age: 1 mg/kg/dose, SC, 12 hourly.</li> </ul> </li> </ul> </li> <li><i>Avoid with renal insufficiency. Monitoring: 0.2–0.4 anti-Xa U/mL (sample must be drawn in a nonheparinised syringe, 3–4 hours post dose).</i></li> <li><b>OR</b></li> <li>• Unfractionated heparin (UFH).               <ul style="list-style-type: none"> <li>» Bolus: 75–100 units/kg IV followed by:</li> <li>» 20 units/kg/hour, IV, as a continuous infusion.</li> </ul> </li> <li><i>Monitoring: PTT 2–3 times baseline value (60–85 seconds). Check platelet count (heparin induced thrombocytopenia is an infrequent complication).</i></li> </ul>	<ul style="list-style-type: none"> <li>▪ Low molecular weight heparin (LMWH), e.g.               <ul style="list-style-type: none"> <li>• Enoxaparin                   <ul style="list-style-type: none"> <li>» &lt; 2 months of age: 1.5 mg/kg/dose, SC, 12 hourly.</li> <li>» &gt; 2 months of age: 1 mg/kg/dose, SC, 12 hourly.</li> </ul> </li> </ul> </li> <li><i>Avoid with renal insufficiency. Monitoring: 0.2–0.4 anti-Xa U/mL (sample must be drawn in a nonheparinised syringe, 3–4 hours post dose).</i></li> </ul>

**Procurement of Therapeutic Alternatives:**

NSN	Product	Supplier	Contract
181870433	Rivaroxaban; 10mg; Tablet; 30 Tablets	Bayer (Pty) Ltd	HP09-2023SD
222001163	Rivaroxaban; 15mg; Tablet; 42 Tablets		
222001433	Rivaroxaban; 20mg; Tablet; 28 Tablets		
222001599	Enoxaparin; 20mg/0.2ml; Syringe, Prefilled; 0.2 ml	Sanofi-Aventis SA (Pty) Ltd	HP06- 2024SVP
180077964	Enoxaparin; 40mg/0.4ml; Syringe, Prefilled; 0.4 ml		
222000901	Enoxaparin; 60mg/0.6ml; Syringe, Prefilled; 0.6 ml		
180970533	Enoxaparin; 80mg/0.8ml; Syringe, Prefilled; 0.8 ml		

Note: The National Department of Health will continue to monitor the supply and availability of UFH and advise when it is restored.

**Circular Dissemination:**

Provinces and Healthcare Facilities are requested to distribute and communicate this information in consultation with the Pharmaceutical and Therapeutics Committees and all other relevant stakeholders.

Kind regards

*K Jamaloodien*  
**MS K JAMALOODIEN**  
**CHIEF DIRECTOR: SECTOR-WIDE PROCUREMENT**  
**DATE: 17/11/2025**