Medicine Guideline for the Safe Use of

FONDAPARINUX

NSW GOVERNMENT Health
South Eastern Sydney Local Health District

Fondaparinux IS A HIGH RISK MEDICINE **USE WITH CAUTION AND ENSURE THE DIRECTIONS WITHIN THIS PROTOCOL ARE FOLLOWED CAREFULLY**	
Areas where Protocol/Guideline applicable	SESLHD
Authorised Prescribers:	Haematologists or Medical Officers under the direct supervision of or in consultation with a Haematologist
Important Safety Considerations	**Fondaparinux should only be used in consultation with Haematology.** • HIT is a complication of heparin therapy with a high rate of thrombotic complications. If the diagnosis is confirmed by a haematologist (or suspected based on assessment using the 4T score) then all forms of heparin (unfractionated and low molecular weight heparins) including heparin flushes, must be discontinued and an alternative anticoagulant started. • Thrombocytopenia is not a contraindication to anticoagulation in patients with HIT and platelet transfusions should be avoided unless critical bleeding. • If the patient is on warfarin, this should be reversed using vitamin K 5mg IV or oral, and not restarted until the platelet count is normal for 2 days. • Patients should be screened for asymptomatic proximal DVT which may influence the duration of anticoagulant therapy.
Indication for use	Treatment of thromboembolic disease in a patient with (or with a history of) Heparin induced Thrombocytopenia (HIT)
Clinical condition	Patients with HIT as diagnosed in consultation with a treating haematologist, based initially on clinical scoring (e.g. 4T score), which may be completed via laboratory testing as time permits. Also, in suspected COVID-19 Vaccine Induced Thrombocytopenia with Thrombosis (treatment as per local therapeutic practice for HIT) This drug is most likely to benefit patients with HIT fulfilling the following criteria; normal or moderately impaired renal function and otherwise clinically stable and a quick offset of anticoagulant effect is not required.
Proposed Place in Therapy	Fondaparinux is a non-heparin anticoagulant used to treat HIT. Alternative anticoagulants used to treat HIT include bivalirudin, danaparoid, argatroban, and lepirudin. Consult haematology regarding choice of therapy for the individual patient. Argatroban and lepirudin are not currently registered in Australia but are available via the TGA Special Access Scheme.
Contra-indications	• Severe renal impairment (creatinine clearance < 30 mL/min) • Active major bleeding • Known hypersensitivity to Fondaparinux sodium • Acute bacterial endocarditis

<table>
<tr><td>Precautions</td><td>

Haemorrhage – can occur at any site. An unexplained fall in blood pressure or haematocrit, or any unexplained symptom, should lead to serious consideration of a haemorrhagic event and cessation of Fondaparinux.
Pregnancy category C: limited safety data is available. Owning to its pharmacological effect fondaparinux may be suspected of causing harmful effects on the human foetus.

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<tr><td>Important Drug Interactions</td><td>Other anticoagulants and drugs that can cause bleeding (e.g. NSAIDs, clopidogrel, antiplatelets, fish oil)
Prolongs INR, will need specific consultation with haematologists when transitioning to oral anticoagulant.</td></tr>
<tr><td>Dosage</td><td>
<table>
<tr><th>Patient weight</th><th>< 50 kg</th><th>51 – 100 kg</th><th>> 100 kg</th></tr>
<tr><td>Subcutaneous dose mg</td><td>5 mg daily</td><td>7.5 mg daily</td><td>10 mg daily</td></tr>
</table>
2.5 mg/0.5 mL injection only is commercially available in Australia.
5 mg/0.4 mL, 7.5 mg/0.6 mL and 10 mg/0.8 mL strengths are commercially available overseas and require SAS category A forms to supply.
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<tr><td>Duration of therapy</td><td>Patient dependent, until platelet recovery (>150 x 109 /L) and/or able to be safely transitioned to an oral anticoagulant.</td></tr>
<tr><td>Prescribing Instructions</td><td>After consultation with Haematology, document the prescribing of fondaparinux on the electronic medication chart.

All medication orders for fondaparinux must include: - Drug, dose, route and indication, the intended duration of therapy and the word “ANTICOAGULANT” printed clearly.</td></tr>
<tr><td>Administration Instructions</td><td>The parts of the syringe with an automatic needle protection system are: needle shield, plunger, finger-grip, security sleeve.
To use the Arixtra syringe,
1 Remove the needle shield, by first twisting it and then pulling it straight off.
2 Discard the needle shield.
3 Gently pinch the skin that has been cleaned to make a fold. Hold the fold between the thumb and the forefinger during the entire injection.
4 Insert the full length of the needle perpendicularly (at an angle of 90°) into the skin fold.
5 Inject all of the content of the syringe by pressing down on the plunger as far as it goes, and then release it: the needle will withdraw automatically from the skin into a security sleeve and then will be locked permanently.
6 Discard the used syringe in a safe manner.
The sites of subcutaneous injection should alternate between the left and the right anterolateral and left and right posterolateral abdominal wall.
To avoid the loss of medicinal product when using the pre-filled syringe do not expel the air bubble from the syringe before injection.</td></tr>
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Monitoring requirements	The anticoagulant effect of fondaparinux is predictable. Routine anticoagulation monitoring is not required in most cases. Monitor signs of bleeding. Specific laboratory monitoring using anti-Xa fondaparinux may be required (range not established, consult haematologist) Platelet count Serum creatinine/eGFR
Management of Complications	• There is no reversal agent for Fondaparinux. • Elimination half-life: 17 hours in healthy young patients and 20 hours in elderly patients • Overdosage associated with bleeding complications should lead to treatment discontinuation and search for the primary cause. Initiation of appropriate therapy which may include surgical haemostasis, blood replacements, fresh plasma transfusion, plasmapheresis should be considered.
Storage requirements	Prefilled syringe contains 2.5 mg/0.5 mL of fondaparinux sodium. Store below 25 °C.
Basis of Protocol/Guideline: (including sources of evidence, references)	1 Cuker A, Arepally G, Chong B, Cines D, Greinacher A, Gruel Y, et al. American Society of Hematology 2018 guidelines for management of venous thromboembolism: heparin-induced thrombocytopenia. Blood Adv. 2018;2(22):3360–92. 2 Nilius H, Kaufmann J, Cuker A, Nagler M. Comparative effectiveness and safety of anticoagulants for the treatments of heparin-induced thrombocytopenia. Am J Hematol. 2021;96:805-815 3 MIMsOnline. Arixtra (Fondaparinux) Product Information. 4 Therapeutic Guidelines. (2021). Anticoagulant therapy. 5 *Australian Medicines Handbook.* Fondaparinux. (2023). 6 *Micromedex.* Fondaparinux. (2021).
Groups consulted in development of this guideline	Intradepartmental discussion amongst all haematologists. SESLHD Pharmacy Services

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GOVERNANCE	
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