Prescribing Protocol SESLHDPR/716 Fondaparinux for Heparin induced Thrombocytopenia (HIT)

Health
South Eastern Sydney
Local Health District

Prescribing Protocol Template for New Drugs	
Title	Fondaparinux for Heparin induced Thrombocytopenia (HIT)
Areas where Protocol/Guideline applicable e.g. District, Hospital, ITU, Ward	Medical Officers, Nurses/Midwives, Pharmacists
Authorised Prescribers	Haematologists or Medical Officers under the direct supervision of a Haematologist
Indication for use	Treatment of thromboembolic disease in a patient with (or with a history of) Heparin induced Thrombocytopenia (HIT)
Clinical condition Patient selection: Inclusion criteria (list investigations necessary and relevant results)	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. 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.
Contra-indications	• Severe renal impairment (creatinine clearance < 30 mL/min) • Active major bleeding • Known hypersensitivity to Fondaparinux sodium • Acute bacterial endocarditis
Precautions	• 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.
Place in Therapy	For patients not fulfilling these criteria, Fondaparinux would not be appropriate. Consider an alternative agent such as Danaparoid, Bivalirudin, Argatroban or a NOAC.
Dosage (Include dosage adjustment for specific patient groups)	**Patient weight** | **< 50 kg** | **51 – 100 kg** | **> 100 kg** **Subcutaneous dose mg** | 5 mg daily | 7.5 mg daily | 10 mg daily 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.
Duration of therapy	Patient dependent, until platelet recovery (>150 x 10^9 /L)and / or able to be safely transitioned to an oral anticoagulant.
Important Drug Interactions	Other anticoagulants. Prolongs INR, will need specific consultation with haematologists when transitioning to oral anticoagulant.

Administration instructions	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.
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)
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
Basis of Protocol/Guideline (including sources of evidence, references)	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. 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 MIMsOnline. Arixtra (Fondaparinux) Product Information. https://www.mimsonline.com.au.acs.hcn.com.au/Search/Search.aspx Last updated 01/05/2020. Therapeutic Guidelines. (2021). Anticoagulant therapy. https://tgldcdp.tg.org.au.acs.hcn.com.au/viewTopic?topicfile=anticoagulant-therapy#MPS_d1e300 *Australian Medicines Handbook.* Fondaparinux. (2021). https://amhonline.amh.net.au.acs.hcn.com.au/chapters/blood-electrolytes/anticoagulants/factor-xa-inhibitors/fondaparinux?menu=hints *Micromedex.* Fondaparinux. (2021). https://www.micromedexsolutions.com.acs.hcn.com.au/micromedex2/librarian/PFDefaultActionId/evidenceexpert.DoIntegratedSearch?navitem=topHome&isToolPage=true#
Groups consulted in development of this protocol	Intradepartmental discussion amongst all haematologists.

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GOVERNANCE	
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Chairperson, QUM Committee	Dr John Shephard
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