# Guidelines for management of bleeding with dabigatran - for possible inclusion into local management protocols

The following guidelines have been prepared by PHARMAC with the assistance of practicing specialists in response to requests for information. They are provided to assist clinical services to develop their own guidelines in accordance with local procedures, and should not be adopted without appropriate review.

- Dabigatran (Pradaxa) is a direct thrombin inhibitor with a half-life of 12-14 hours.
- Dabigatran is primarily renally excreted and the half-life is prolonged in renal impairment.
- The major adverse effect of all anticoagulant medications is bleeding.
- Two issues should be considered in managing bleeding events with dabigatran:
  - Control bleeding and provide general support for haemodynamic state; and
  - Attempt to reverse the anticoagulant effect where life-threatening bleeding is present.

**Dabigatran associated bleeding**

- **Initiate standard resuscitation measures**
- Check coagulation screen including activated partial thromboplastin time (aPTT), thrombin time (TT) and fibrinogen assay. Indicate time of last dabigatran dose when requesting test.
- Check full blood count, renal function and electrolytes (including calcium).

**There is no specific reversal agent for dabigatran currently and its anticoagulant effect will not be reversed by administration of vitamin K or plasma infusion.**

**STOP dabigatran therapy**

## Mild bleeding

- Local haemostatic measures
  - Mechanical compression
  - Tranexamic acid orally/topically, 15mg/kg four times a day
- Delay next dose of dabigatran or discontinue treatment as appropriate

## Moderate to Severe bleeding[a]

- **Consult Haematology service**
- Local measures
  - Mechanical compression
  - Consider surgical intervention or wound packing
- Fluid replacement
  - Maintain good urine output as dabigatran excreted renally
- Blood product transfusion
  - Consider platelets if levels less than 70-80 X $10^9$ /L or patient on anti-platelet agent
- Administration of anti-fibrinolytic agent
  - Tranexamic acid IV (15-30mg/kg) +/- continuous infusion (1mg/kg/hr)
- Oral charcoal application if dabigatran ingestion <2 hours ago
- Consider Prothrombinex-VF 25-50 iu/kg[c]. Repeat if necessary with Haematology guidance

## Life threatening bleeding[b]

Implement measures for Moderate to Severe bleeding and consider:

- Recombinant factor VIIa (Novoseven) (100mcg/kg by iv bolus)[c]. Repeat if necessary with Haematology guidance
- Haemodialysis especially if renal failure present

[a]**Moderate to Severe bleeding** – reduction in Hb ≥ 20g/L, transfusion of ≥ 2 units of red cells or symptomatic bleeding in critical area or organ (for example, intraocular, intracranial, intraspinal, intramuscular with compartment syndrome, retroperitoneal, intraarticular or pericardial bleeding).

[b]**Life-threatening bleeding** – symptomatic intracranial bleed, reduction in Hb ≥ 50g/L, transfusion of ≥ 4 units of red cells, hypotension requiring inotropic agents or bleeding requiring surgical intervention.

[c]The potential use of Prothrombinex-VF and recombinant factor VIIa (Novoseven) is based on preclinical data.

New Zealand Government

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