Open Book
Learning from close calls and adverse events

ALERT: Prescribing error – dabigatran and enoxaparin

This report alerts providers to adverse event cases reported to the Commission's Adverse Events Learning Programme. It highlights the risks when prescribers are unaware of the requirements for prescribing dabigatran or switching between enoxaparin[1] (Clexane) and dabigatran[2] (Pradaxa). The requirements are different to when starting warfarin or switching between warfarin and enoxaparin.

Several cases have been identified where dabigatran and enoxaparin were administered concurrently, placing patients at **high risk of bleeding**. **These risks apply to all low-molecular-weight heparins (LMWHs) and non-vitamin K antagonist (non-VKA) oral anticoagulants, when used together.**

We advise providers to consider this report, determine risks within their own organisations and make systems changes as necessary.

This report is relevant to:

- prescribers
- clinical staff administering medication
- pharmacists and pharmacy staff
- quality improvement, clinical risk and patient safety managers.

Case 1 – SAC[3] 4

A 42-year-old patient was taking dabigatran for recurrent thrombosis. On admission, the patient was co-prescribed enoxaparin with dabigatran. The patient received both medicines for four days before the error was identified and enoxaparin discontinued. The patient was closely monitored for bleeding but did not exhibit any signs.

Case 2 – SAC 4

A 76-year-old patient newly initiated on dabigatran was administered enoxaparin at 0700 hours by night staff and dabigatran at 0800 hours by morning staff. The patient therefore received both anticoagulants within a one-hour interval. The patient was closely monitored for bleeding but did not exhibit any signs.

Case 3 – SAC 1

A 75-year-old patient was admitted with suspected transient ischaemic attack. The patient developed a pulmonary embolism and was commenced on enoxaparin and dabigatran. Subsequently, the patient developed bilateral subdural haemorrhage extending into the brainstem and died.

Case 4 – Inpatient audit results

An audit of one district health board's inpatient records showed 50 percent of patients receiving dabigatran therapy were also co-prescribed and given at least one dose of enoxaparin inappropriately with dabigatran.

[1] Enoxaparin is a low-molecular-weight heparin (LMWH). This alert is relevant to all LMWH medicines.
[2] Dabigatran is a non-vitamin K oral anticoagulant. This alert is relevant to all non-VKA oral anticoagulant medicines.
[3] Abbreviation of Severity Assessment Code.

Case 5 – SAC 2

A patient had their regular dabigatran stopped for a therapeutic endoscopic procedure. An incidental medical finding during treatment required a course of enoxaparin. Dabigatran was re-started, resulting in the patient being on both enoxaparin and dabigatran concurrently for a period of approximately 24 hours. Following discharge from hospital, the patient later had a complication resulting in a gastro-intestinal bleed. Whilst this complication was not caused by the co-prescribed anticoagulants, it was likely more serious than it would have been.

Dabigatran

What is dabigatran?

Dabigatran is a direct thrombin inhibitor. It has a rapid onset of action, which means, unlike warfarin, a full anticoagulant effect is achieved after ONE therapeutic dose. Other non-VKA oral anticoagulants include rivaroxaban and apixaban, both of which are factor Xa inhibitors and have a fast onset of action.

If non-VKA oral anticoagulants and LMWHs are co-prescribed/administered the patient will be at increased risk of a significant bleeding event.

How do I switch patients from enoxaparin to dabigatran?

Enoxaparin and dabigatran should **never** be used together.

They should only be used **sequentially** (ie, give a dose of dabigatran when the next dose of enoxaparin is due). **There is no need to have any cross-over of therapy.**

Health Quality & Safety Commission comment

- Providers with electronic prescribing systems are strongly encouraged to build in alerts or stops to prevent prescribers co-prescribing LMWHs and non-VKA oral anticoagulants.
- Have clear organisational guidance for all prescribers and administrators relating to anticoagulation. Guidance should cover starting a patient on anticoagulation and which anticoagulant should be used for specific indications. The guideline should also cover the management of patients who are going to be nil by mouth and need an LMWH prescribed, and/or are having surgery.
- The term ‘bridging’ can mean different things to different specialties within health. Use the term ‘switching’ instead, in line with the datasheet.
- The datasheet for dabigatran is on the Medsafe website at: www.medsafe.govt.nz/profs/datasheet/p/Pradaxacap.pdf.
- Do you know if there is co-prescribing of these two high-risk medicines in your organisation? Consider undertaking an audit/review, as in Case 4.
- Review clusters of SAC 3–4-rated adverse events or near misses where there may be high risk of harm or valuable learning locally and nationally. This is a proactive patient safety approach.
- The Centre for Adverse Reactions Monitoring (CARM) collects data about adverse bleeding events experienced by patients using non-VKA oral anticoagulants. You can report directly to CARM online at: https://nzphvc-01.otago.ac.nz/carm.
- The Medication Error Reporting Programme (MERP) collects and analyses voluntary reports from health professionals of actual and near-miss medication errors in primary care. You can report directly to MERP online at: https://nzphvc.otago.ac.nz/merp.
- Idarueizumab (Praxbind) is the specific reversal agent for dabigatran when rapid reversal of the anticoagulant effect is required www.medsafe.govt.nz/profs/Datasheet/p/praxbindinj.pdf.