

DABIGATRAN - SAFE PRESCRIBING - NOT A MAGIC BULLET

- ▶ EDUCATE PATIENTS TO REPORT ANY BLEEDING IMMEDIATELY
- ▶ THERE IS NO ANTIDOTE - BLEEDING MAY REQUIRE URGENT REFERRAL
- ▶ CHECK RENAL FUNCTION BEFORE PRESCRIBING - USE CORRECT DOSE
- ▶ CONSIDER POTENTIAL INTERACTIONS AND ADVERSE EFFECTS
- ▶ FUNDED FOR ATRIAL FIBRILLATION (AF) AND PREVENTION OF VENOUS THROMBOEMBOLISM (VTE) AFTER MAJOR ORTHOPAEDIC SURGERY
- ▶ GOOD COMPLIANCE IS VITAL

Dabigatran etexilate is a direct thrombin inhibitor, funded for AF (prevention of stroke, embolism and reduction of vascular mortality) and for prophylaxis of VTE post major orthopaedic surgery.

Educate patients to report any bleeding immediately.

Avoid in patients with haemorrhagic risk factors e.g. gastrointestinal bleeding, recent trauma, stroke (within 6 months) or following brain, spinal or ophthalmic surgery. As with all anticoagulants, there is a risk of bleeding.

There is no antidote for dabigatran, unlike vitamin K for warfarin. Monitor for signs of bleeding at each appointment and be aware of signs of anaemia. If bleeding, discontinue dabigatran, check TT and aPTT and discuss with a haematologist or cardiologist.

Check renal function before prescribing and do not give dabigatran to patients with a creatinine clearance (CrCl) of less than 30ml/min. Older adults with AF and others who have a compromised renal function (CrCl 30-50ml/min), should be prescribed a lower dose (see dosing box).

NOTE: Do not rely on the laboratory reported eGFR; calculate CrCl before prescribing.

Consider potential interactions before prescribing.

Ketoconazole and rifampicin should be avoided; use extreme care with amiodarone and verapamil. There are many potential interactions with other agents including St John's Wort and carbamazepine. Concomitant clopidogrel and aspirin will increase the risk of bleeding; caution is advised with NSAIDs.

NOTE: There is a higher prevalence of dyspepsia (11%) with dabigatran compared to warfarin (5%).

Atrial fibrillation (AF) indication. Dabigatran may be a useful alternative for patients who are not managing the monitoring requirements for warfarin, or are not well controlled. Be aware that the bleeding risk of dabigatran is similar to warfarin. Patients who are currently prescribed aspirin instead of warfarin, because of concerns about interactions or managing regular testing, may benefit from dabigatran instead of aspirin. If unsure, do not change from warfarin without specialist advice.

NOTE: Dabigatran is not currently licensed for use in patients with mechanical valves or valve disease.

Prevention of venous thromboembolism (VTE) indication.

Dabigatran may be considered for patients who need short term prophylaxis **after** orthopaedic surgery. For this indication, dosing is once daily (see dosing box).

NOTE: Dabigatran is not licensed for the treatment or long term prophylaxis of VTE.

Good compliance is vital because there is a rapid loss of effect if doses are missed. Make sure the patient understands the importance of good compliance.

Due to a rapid loss of chemical stability once opened, dabigatran is not suitable for re-packing into compliance aids. The capsules must be swallowed whole.

➔ continued

DABIGATRAN

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DOSING INFORMATION

ATRIAL FIBRILLATION

(Prevention of stroke, systemic embolism and reduction of vascular mortality)

150mg twice daily

Adults over 80 years* 110mg twice daily

Renal impairment

Moderate renal impairment (CrCl 30-50ml/min)

110mg twice daily

Severe renal impairment (CrCl <30ml/min)

Do not prescribe

PREVENTION OF VTE following major orthopaedic surgery

Knee replacement surgery

110mg within 1-4 hours of completed surgery, then 220mg once daily for 10 days

Hip replacement surgery

110mg within 1-4 hours of completed surgery, then 220mg once daily for 28-35 days

Renal impairment

Moderate renal impairment (CrCl 30-50ml/min)

150mg once daily

Severe renal impairment (CrCl <30ml/min)

Do not prescribe

*Due to an expected age-related decline in renal function

KEY REFERENCES

Dabigatran information for clinicians. <http://www.pharmac.govt.nz/2011/06/15/BPAC%20Dabig%20insert.pdf> (Accessed 16-06-11)
Boehringer Ingelheim (NZ) Limited. Dabigatran etexilate Pradaxa[®]
New Zealand Datasheet 11-02-11 (Accessed 16-06-11)

NOTE: The majority of dosing data is for patients weighing between 50 and 100kg.

There is currently no information on dosing or safety in those under 18 years, in pregnancy or lactation.

[CLICK HERE FOR FURTHER INFORMATION ON DABIGATRAN AND A FULL REFERENCE LIST](#)

For further information on other high-risk medicines visit our website at: www.saferx.co.nz

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