When used for *treatment of deep-vein thrombosis and pulmonary embolism, prophylaxis of recurrent deep-vein thrombosis and pulmonary embolism, prophylaxis of stroke and systemic embolism in non-valvular atrial fibrillation,* consider reduced dose of 110–150 mg twice daily if creatinine clearance 30–50 mL/minute, based on individual assessment of thromboembolic risk and risk of bleeding.

Monitoring In renal impairment monitor renal function at least annually (manufacturer recommends Cockroft and Gault formula to calculate creatinine clearance).

- **MONITORING REQUIREMENTS**
  - Patients should be monitored for signs of bleeding or anaemia; treatment should be stopped if severe bleeding occurs.
  - No routine anticoagulant monitoring required (INR tests are unreliable).
  - Assess renal function (manufacturer recommends Cockroft and Gault formula to calculate creatinine clearance) before treatment in all patients and at least annually in elderly.
- **DIRECTIONS FOR ADMINISTRATION** When given concomitantly with amiodarone or verapamil, doses should be taken at the same time.
- **PRESCRIBING AND DISPENSING INFORMATION** Dabigatran etexilate, is given orally for prophylaxis of venous thromboembolism in adults after total hip replacement or total knee replacement surgery; it is also licensed for the treatment of deep-vein thrombosis and pulmonary embolism, and prophylaxis of recurrent deep-vein thrombosis and pulmonary embolism in adults. Duration of treatment should be determined by balancing the benefit of treatment with the bleeding risk; shorter duration of treatment (at least 3 months) should be based on transient risk factors i.e recent surgery, trauma, immobilisation, and longer duration of treatment should be based on permanent risk factors, or idiopathic deep-vein thrombosis or pulmonary embolism.
- **PATIENT AND CARER ADVICE** Patients should be provided with an alert card and advised to keep it with them at all times.
- **NATIONAL FUNDING/ACCESS DECISIONS**

NICE decisions

- **Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults (September 2008)** NICE TA157
  Dabigatran etexilate (*Pradaxa*®) is an option for the prophylaxis of venous thromboembolism in adults after total hip replacement or total knee replacement surgery.
  www.nice.org.uk/guidance/ta157
- **Dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation (March 2012)** NICE TA249
  Dabigatran etexilate (*Pradaxa*®) is an option for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation and with one or more of the following risk factors:
  - previous stroke, transient ischaemic attack, or systemic embolism
  - left ventricular ejection fraction <40%
  - symptomatic heart failure of New York Heart Association (NYHA) class 2 or above
  - age ≥75 years
  - age ≥65 years in patients with diabetes mellitus, coronary artery disease, or hypertension

  The risks and benefits of dabigatran compared to warfarin should be discussed with the patient.
  www.nice.org.uk/guidance/ta249
- **Dabigatran etexilate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism (December 2014)** NICE TA327
  Dabigatran etexilate (*Pradaxa*®) is recommended, within its marketing authorisation, as an option for treating and for preventing recurrent deep vein thrombosis and pulmonary embolism in adults.
  www.nice.org.uk/guidance/ta327

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Capsule

CAUTIONARY AND ADVISORY LABELS 10, 25

- **Pradaxa** (Boehringer Ingelheim Ltd)
  Dabigatran etexilate (as Dabigatran etexilate mesilate) 75 mg Pradaxa 75mg capsules | 10 capsule PoM £8.50 | 60 capsule PoM £51.00 DT = £51.00
  Dabigatran etexilate (as Dabigatran etexilate mesilate) 110 mg Pradaxa 110mg capsules | 10 capsule PoM £8.50 | 60 capsule PoM £51.00 DT = £51.00
  Dabigatran etexilate (as Dabigatran etexilate mesilate) 150 mg Pradaxa 150mg capsules | 60 capsule PoM £51.00 DT = £51.00

ANTITHROMBOTIC DRUGS › TISSUE PLASMINOGEN ACTIVATORS

F 229

Urokinase

15-Nov-2019

- **INDICATIONS AND DOSE**

Deep-vein thrombosis (thromboembolic occlusive vascular disease)

- BY INTRAVENOUS INFUSION
- Adult: Initially 4400 units/kg, to be given over 10–20 minutes, followed by 100 000 units/hour for 2–3 days

Pulmonary embolism (thromboembolic occlusive vascular disease)

- BY INTRAVENOUS INFUSION
- Adult: Initially 4400 units/kg, to be given over 10–20 minutes, followed by 4400 units/kg/hour for 12 hours

Occlusive peripheral arterial disease (thromboembolic occlusive vascular disease)

- BY INTRA-ARTERIAL INFUSION
- Adult: (consult product literature)

Occluded central venous catheters (blocked by fibrin clots)

- BY INTRAVENOUS INJECTION
- Adult: Inject directly into occluded catheter, to be dissolved in sodium chloride 0.9% to a concentration of 5000 units/mL; use a volume sufficient to fill the catheter lumen; leave for 20–60 minutes then aspirate the lysate; repeat if necessary

Occluded arteriovenous haemodialysis shunts (blocked by fibrin clots)

- BY INTRAVENOUS INFUSION, OR BY INTRA-ARTERIAL INFUSION
- Adult: (consult product literature)

SYNER-KINASE ®

Deep-vein thrombosis (thromboembolic occlusive vascular disease)

- BY INTRAVENOUS INFUSION
- Adult: Initially 4400 units/kg, to be given over 10 minutes, dose to be made up in 15 mL sodium chloride 0.9%, followed by 4400 units/kg/hour for 12–24 hours

Pulmonary embolism (thromboembolic occlusive vascular disease)

- INITIALLY BY INTRAVENOUS INFUSION
- Adult: Initially 4400 units/kg, to be given over 10 minutes, dose to be made up in 15 mL sodium chloride 0.9%, followed by (by intravenous infusion) 4400 units/kg/hour for 12 hours, alternatively (by intra-arterial injection) initially 15 000 units/kg, to be injected into pulmonary artery, subsequent doses