Boehringer Ingelheim is pleased to provide you with this Educational Pack, which has been developed to give practical and relevant information on the appropriate use of Pradaxa®.
The pack includes:

- Pradaxa® 110mg b.d – Summary of Product Characteristics
- Pradaxa® 75mg b.d. – Summary of Product Characteristics
- Prescriber Guide – this addresses recommendations for the use of Pradaxa® in order to minimize the risk of bleeding
- Patient Alert Card

To order additional copies of the Patient Alert Card please go to:
www.pradaxa.co.uk/pVTEeducationalpack

You can also order or download this Educational Pack.

References:

1. Boehringer Ingelheim. Pradaxa® 110mg SPC. 2011.
2. Boehringer Ingelheim. Pradaxa® 75mg SPC. 2011.

Prescribing Information (pVTEp UK) – PRADAXA®▼ (dabigatran etexilate)

Capsules containing 75mg or 110mg dabigatran etexilate (as mesilate) **Action:** Direct thrombin inhibitor **Indication:** Primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip or knee replacement surgery **Dose and Administration:** Recommended dose is 220 mg once daily orally taken as 2 capsules of 110 mg. Initiate treatment within 1-4 hours of completed surgery with a single capsule continuing with 2 capsules once daily for a total of 10 days (knee replacement surgery) or 28 – 35 days (hip replacement surgery). Delay initiation of treatment if haemostasis is not secured. If treatment is not started on the day of surgery, initiate with 2 capsules once daily. In patients with moderate renal impairment (CrCL 30-50 ml/min); the elderly (age > 75 years); concomitant amiodarone, quinidine or verapamil (take at the same time as Pradaxa) the recommended dose is 150 mg once daily; moderate renal impairment and concomitant verapamil consider 75 mg daily. Pradaxa is contraindicated in severe renal impairment (CrCL < 30 ml/min). Not recommended if liver enzymes > 2 Upper Limit of Normal (ULN). No dose adjustment required but close clinical surveillance in patients <50 kg or >110 kg. If switching from Pradaxa to parenteral anticoagulant wait 24 hours after the last dose of Pradaxa; if switching from parenteral anticoagulants to Pradaxa then Pradaxa should be given 0-2 hours prior to the time that the next dose of the alternate therapy would be due, or at the time of discontinuation in case of continuous treatment. Not recommended aged < 18 years. Pradaxa should be swallowed whole with water, with or without food. Patients should be instructed not to open the capsule as this may increase the risk of bleeding. **Contraindications:** Hypersensitivity to any component; severe renal impairment (CrCL < 30 ml/min); active clinically significant bleeding; organic lesion at risk of bleeding; impairment of haemostasis; hepatic impairment or liver disease expected to have any impact on survival; concomitant systemic ketoconazole, cyclosporine, itraconazole, tacrolimus. **Warnings and Precautions:** Not recommended if liver enzymes > 2 ULN. Haemorrhagic risk: Close clinical surveillance (signs of bleeding or anaemia) is recommended throughout the treatment period, especially when haemorrhagic risk is increased or risk factors combined. Factors which may increase haemorrhagic risk: age ≥ 75 years; moderate renal impairment (CrCL 30 – 50 ml/min); P-glycoprotein inhibitor co-medication; body weight < 50 kg; acetylsalicylic acid (aspirin); NSAID; clopidogrel; diseases/procedures associated with a risk of bleeding such as coagulation disorders, thrombocytopenia or functional platelet defects, active ulcerative GI disease, recent GI bleeding, recent biopsy or major trauma, recent ICH or brain, spinal or ophthalmic surgery, bacterial endocarditis. The measurement of dabigatran related anticoagulation may be helpful to avoid excessive high exposure to dabigatran in the presence of additional risk factors. Patients who develop acute renal failure must discontinue Pradaxa. If severe bleeding occurs, discontinue treatment and investigate the source of the bleeding. Avoid or use with caution agents which may increase the risk of haemorrhage. Avoid concomitant administration with P-gp inducers. Patients on dabigatran etexilate who undergo surgery or invasive procedures are at increased risk for bleeding therefore surgical interventions may require the temporary discontinuation of dabigatran etexilate; prescribers should consult the Summary of Product Characteristics for further information. Procedures such as spinal anaesthesia may require complete haemostatic function. The risk of spinal or epidural haematoma may be increased in cases of traumatic or repeated puncture and by the prolonged use of epidural catheters. After removal of a catheter, an interval of at least 2 hours should elapse before the administration of the first dose of dabigatran etexilate; these patients require frequent observation for neurological signs and symptoms of spinal or epidural haematoma. Treat with caution patients at high surgical mortality risk and with intrinsic risk factors for thromboembolic events. No data on the use of Pradaxa in patients undergoing hip fracture surgery, therefore treatment not recommended. Contains Sunset Yellow (E110) which may cause allergic reactions. **Interactions:** Anticoagulants and antiplatelet aggregation agents; strong P-gp inhibitors co-administration (close clinical surveillance): amiodarone, quinidine, verapamil reduce Pradaxa dose to 150mg (see above); consider dose reduction to 75mg daily in patients with both moderate renal impairment and on verapamil; close monitoring with clarithromycin; not recommended for concomitant treatment: posaconazole, dronedarone, protease inhibitors including ritonavir and its combinations with other protease inhibitors; avoid with P-gp inducers e.g. rifampicin, St John's wort, carbamazepine, phenytoin. Dabigatran etexilate and dabigatran are not metabolised by cytochrome CYP450 system, therefore related medicinal product interactions not expected. Pantoprazole and other proton-pump inhibitors (PPI) were co-administered with Pradaxa in clinical trials and concomitant PPI treatment did not appear to reduce the efficacy of Pradaxa. Ranitidine administration together with Pradaxa had no clinically relevant effect on the extent of absorption of dabigatran. **Fertility, pregnancy and lactation:** Avoid pregnancy during treatment. Do not use in pregnancy unless clearly necessary. Discontinue breast-feeding during treatment **Undesirable effects:** Most commonly reported adverse reactions occurring in total in approximately 14% of patients treated short-term for elective hip or knee replacement surgery ; major bleeds, including wound site bleedings < 2%. Common (≥ 1/100, <1/10): anaemia; haemoglobin decreased; epistaxis; gastrointestinal haemorrhage; abdominal pain; diarrhoea; dyspepsia; nausea. Prescribers should consult the Summary of Product Characteristics for further information on side effects. **Pack sizes and NHS price:** 75mg 10 capsules £xx; 60 capsules £xx 110mg 10 capsules £xx; 60 capsules £xx **Legal category** POM **MA numbers:** 75mg EU/1/08/442/001 (10 capsules); EU/1/08/442/003 (60 capsules) 110mg EU/1/08/442/005 (10 capsules); EU/1/08/442/007 (60 capsules) **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. **Prepared in** June 2011.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone).

Boehringer Ingelheim

Date of preparation: June 2011 Job code: DBG 2654

PRADAXA®▼ (DABIGATRAN ETEXILATE)

EDUCATIONAL PACK

For primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery[1,2]