



## Newsletter Spring/Summer 2013

### National Thrombosis Week

Already we are heading towards the middle of the year and summer is almost upon us. May got going with National Thrombosis Week (6<sup>th</sup>-10<sup>th</sup> May). CLOT has been very keen to know what you have all been doing to spread the word and it's not too late to tell us of any special events or educational activities that have taken place nationally to raise awareness. We would love to hear from you so log on to the website to find out what some of our members have been up to and to share your experience.

### ISTH Nursing Forum 2013

The time is almost here for ISTH 2013 being held in Amsterdam from June 29<sup>th</sup> – July 4<sup>th</sup>. CLOT encourages all members to consider attending this important event. There are greatly reduced registration fees for nurses so don't delay booking! You can find out further information through our link via the CLOT website. CLOT committee members will be attending this year and look forward to seeing as many CLOT members as possible. This is a great opportunity to share knowledge and experience as well as network with other nurses.

### CLOT Conference 2013

This year's conference is to be held on the 18<sup>th</sup> October at a venue yet to be arranged. Further details will follow and will be available on the CLOT website and via email in due course.

### Calling all CLOT Members...

A vacancy has become available on the executive committee and CLOT is looking to recruit a new member for the position of Conference Secretary. If you feel that you could make a valuable contribution to the committee, please get in touch with us. It is a commitment on top of your normal work role but is a great opportunity to be involved nationally with healthcare professionals working in the speciality. It also provides continuing professional development.

For further details please contact Caroline through the CLOT website.

## Conference Workshop 2013

As most members are now aware, there are usually workshops incorporated into the annual conference and this year is no different.

To help promote greater debate and share best practice, CLOT would like to encourage all members to visit the website forum to discuss this years topics. We have focused most attention on the new oral anticoagulants and would love to hear from you all on how you are managing in your specialist areas.

So please join us on the forum to share your thoughts and ideas. The following questions open to debate are:

1. Help! We are losing our role as anticoagulant nurses.
2. How to give bridging therapy with the new oral anticoagulants?
3. How do you switch from warfarin to the new oral anticoagulants?
4. How do you implement NICE CG144?
5. How do you care for patients with superficial thrombophlebitis?
6. Legal case studies.

We look forward to hearing from you on the CLOT website forum.

## CLOT Website

Don't forget to log onto our website to keep up to date with the latest goings on in the world of anticoagulation and thrombosis.

CLOT is free to join and provides its members with a range of online services including CLOT Net Online Networking Forum, CLOT Links Online Service Information Directory, CLOT Swot Online Certificated Learning and access to grants to assist with personal or service development as well as an opportunity to apply for an educational / travel scholarship worth up to £2,000. The scholarship can contribute towards a development in a service or an attendance at a national / international conference of relevance such as ISTH. Conditions of the scholarship are that members send a letter of application explaining how and why they would utilise the money. In return all we ask is that the successful candidate does a small presentation at the annual CLOT conference and share the experience with fellow CLOT members.

For more information on applying for the scholarship or for any of the other services listed above, please log on to the CLOT website.

## Sponsors

We would like to give a huge thank you to our GOLD sponsors, Boehringer Ingelheim and Bayer for their much valued continued support of CLOT.

A message from our sponsors



Heartmind™ – support what matters

Concordance with long-term therapies averages only 50%, according to the World Health Organisation.<sup>1,2</sup>

For 50 years, warfarin has been the standard anticoagulant treatment to reduce the risk of stroke in patients with atrial fibrillation (AF). For warfarin to achieve the best possible results, in terms of preventing stroke while minimising bleed risk, a patient's international normalised ratio (INR) needs to be within therapeutic range (INR 2–3) for at least 70% of the time.<sup>3</sup> In practice, this may be quite challenging to achieve.

Heartmind™ is a free patient support programme designed to improve concordance in patients prescribed Pradaxa® (dabigatran etexilate) for stroke prevention in nonvalvular atrial fibrillation (AF) by addressing the barriers to concordance reported in published literature.<sup>4,5</sup>

By educating patients about their condition, how their medication works and what to expect from their treatment, heartmind™ aims to empower patients to take greater interest in their condition and control of their medication. Through sharing advice on topics such as coping strategies with lifestyle advice and patient and carer stories, heartmind™ aims to motivate patients to remain concordant.

For healthcare professionals, heartmind™ can complement the care already provided. The programme reinforces existing healthcare support and by providing a personalised programme of content, patients who require extra support will receive it, with a focus on those topics that are most important to each patient.

Heartmind™ is a six-month programme comprising magazines, fast fact brochures, a comprehensive website, and dosing reminder items such as SMS messages, emails, 12-hour alarms and more. By aiming to improve patient concordance, it can help patients change their behaviour and optimise their long-term treatment.

The programme has been developed by Boehringer Ingelheim, in association with Anticoagulation Europe and the AF Association.

**To learn more, visit the Heartmind™ website [www.heart-mind.co.uk](http://www.heart-mind.co.uk) and register using the healthcare professional password “heartmind”.**

#### References

1. WHO 2003 <http://www.who.int/chp/knowledge/publications/adherence/report/en>
2. Haynes RB *et al.* Interventions for enhancing medication adherence. Cochrane Database of systematic reviews 2008, issue 2.
3. Morgan C *et al.* Warfarin treatment in patient with atrial fibrillation. Observing outcomes associated with varying levels of INR control. *Thrombosis research* 2009; 124:37-41
4. Lip G *et al.* Ethnic differences in patient perceptions of atrial fibrillation and anticoagulation therapy. *Stroke* 2002; 33: 238-2425. Steed L *et al.* An examination of the self-regulation model in atrial fibrillation. *Brit J Health Psych* 1999; 4: 337-347
5. Steed L *et al.* An examination of the self-regulation model in atrial fibrillation. *Brit J Health Psych* 1999; 4: 337-347

Job code: UK/DBG-131198

Date of preparation: May 2013

## **Prescribing Information (SPAF - UK)**

### **PRADAXA® (dabigatran etexilate)**

Capsules containing 110 mg or 150 mg dabigatran etexilate (as mesilate)

**Action:** Direct thrombin inhibitor **Indication:** Prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation with one or more of the following risk factors: Previous stroke, transient ischaemic attack, or systemic embolism (SEE); Left ventricular ejection fraction < 40 %; Symptomatic heart failure, ≥ New York Heart Association (NYHA) Class 2; Age ≥ 75 years; Age ≥ 65 years associated with one of the following: diabetes mellitus, coronary artery disease, or hypertension

**Dose and Administration:** Renal function should be assessed by calculating CrCL prior to initiation to exclude patients with severe renal impairment (CrCL < 30 mL/min). Recommended daily dose 300 mg taken as one 150 mg capsule twice daily. Therapy should be continued long term. In case of intolerability to dabigatran, patients should be instructed to immediately consult their doctor. Elderly: Aged ≥ 80 years 220 mg taken as one 110 mg capsule twice daily; 75 – 80 years consider 220 mg taken as one 110 mg capsule twice daily. As renal impairment may be frequent in the elderly (> 75 years), assess renal function by calculating CrCL prior to initiation to exclude patients with severe renal impairment (CrCL < 30 mL/min). Renal function should also be assessed at least once a year or more frequently as needed in certain clinical situations when it is suspected that the renal function could decline or deteriorate. Patients with an increased risk of bleeding: closely monitor clinically looking for signs of bleeding or anaemia. Dose adjustment should be decided at the discretion of the physician, following assessment of the potential benefit and risk to an individual patient. A coagulation test may help identify increased risk patients. Patients with gastritis, oesophagitis, or gastroesophageal reflux consider 220 mg taken as one 110 mg capsule twice daily due to the elevated risk of major gastro-intestinal bleeding. Renal impairment: contraindicated in severe renal impairment (CrCL < 30 mL/min); patients with renal impairment and a high risk of bleeding consider 220 mg taken as one 110 mg capsule twice daily. Close clinical surveillance is recommended in patients with renal impairment. As above assess renal function prior to initiation to exclude patients with severe renal impairment and assess renal function at least once a year or more frequently as needed. Concomitant verapamil 220 mg taken as one 110 mg capsule twice daily; Pradaxa and verapamil should be taken at the same time. No dose adjustment required but close clinical surveillance in patients < 50 kg. Not recommended if liver enzymes > 2 Upper Limit of Normal (ULN). If switching from Pradaxa to parenteral anticoagulant wait 12 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; if switching from Pradaxa to VKA adjust the starting time of the VKA based on CrCL; if switching from VKA to Pradaxa stop VKA and give Pradaxa once INR < 2.0. Cardioversion patients can stay on Pradaxa whilst being cardioverted. No relevant use of Pradaxa in the paediatric population in the indication. 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; lesion or condition at significant risk of major bleeding such as current or recent gastrointestinal ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities; concomitant treatment with any other anticoagulants e.g. unfractionated heparin (UFH), low molecular weight heparins (enoxaparin, dalteparin etc), heparin derivatives (fondaparinux etc), oral anticoagulants (warfarin, rivaroxaban, apixaban etc) except under the circumstances of switching therapy to or from Pradaxa or when UFH is given at doses necessary to maintain an open central venous or arterial catheter; hepatic impairment or liver disease expected to have any impact on survival; concomitant systemic ketoconazole, cyclosporine, itraconazole, tacrolimus, dronedarone; prosthetic heart valves requiring anticoagulant treatment. **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; selective serotonin re-uptake inhibitors (SSRIs) or selective serotonin norepinephrine re-uptake inhibitors (SNRIs); other drugs which may impair haemostasis; diseases/procedures associated with a risk of bleeding such as coagulation disorders, thrombocytopenia or functional platelet defects, recent biopsy, major trauma, bacterial endocarditis, oesophagitis, gastritis or gastroesophageal reflux. 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 medicinal products which may increase the risk of haemorrhage. The use of fibrinolytic medicinal products for the treatment of acute ischaemic stroke may be considered if the patient presents with a dTT, ECT or aPTT not exceeding the ULN according to the local reference range. 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. Myocardial infarction. Contains Sunset Yellow (E110) which may cause allergic reactions. **Interactions:** Anticoagulants and antiplatelet aggregation medicinal products; Strong P-gp inhibitors e.g. amiodarone, quinidine, verapamil, clarithromycin co-administration (close clinical surveillance); verapamil co-administration - reduce Pradaxa dose to 220 mg (see above); not recommended for concomitant treatment posaconazole, 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; SSRIs or SNRIs. 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 are bleedings occurring in total in approximately 16.5 % in patients with atrial fibrillation treated for the prevention of stroke and SEE. Common (≥ 1/100 to <1/10): anaemia; epistaxis; gastrointestinal haemorrhage; abdominal pain; diarrhoea; dyspepsia; nausea; hepatic function abnormal/liver function test abnormal; genitouriological haemorrhage. Prescribers should consult the Summary of Product Characteristics for further information on side effects. **Pack sizes and NHS price:** 110 mg 60 capsules £65.90 150 mg 60 capsules £65.90 **Legal category** POM **MA numbers:** 110 mg EU/1/08/442/007 (60 capsules) 150 mg EU/1/08/442/011 (60 capsules) **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, Binger Str. 173, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. **Prepared in February 2013.**

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