Dabigatran (Pradaxa) Label Updated

Pradaxa (dabigatran) was approved by the FDA in 2010 as an alternative to warfarin. Both PRADAXA and warfarin are oral anticoagulants. These blood-thinning medicines help to stop clots by targeting factors your blood needs to form clots. PRADAXA and warfarin work differently to help reduce the risk of stroke due to A-Fibrillation not caused by a heart valve problem. Pradaxa requires no routine INR testing nor any periodic dosing adjustments, as does warfarin.

In November 2011, the manufacture of Dabigatran (Pradaxa) announced a revision of their drug label. This updated drug label includes information on the storage and handling of dabigatran.

The label now states that, once opened, dabigatran can be safely *stored* and *used* for <u>four months</u>, (longer than the previous recommendation to use the medication *within 30 days* of opening the bottle)



Pradaxa is a nonformulary medication at Harlem Hospital and is restricted to Cardiac Dept. only. In addition, the new label also states that renal function should be assessed prior to starting therapy and tested annually in patients 75 years of age and those with creatinine clearance (CrCl) <50 mL/min. This warning comes after several reports were made concerning Pradaxa's anticoagulant activity and half-life was shown to be increased in patients with renal impairment.

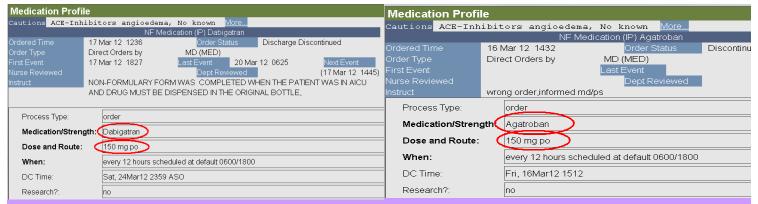
Since Pradaxa has been out in the market, numerous concerns have been raised over the drug's safety such as increased incidence of serious and even fatal bleeding events. Additionally, there is no reversal agent for Pradaxa.

The FDA is continuing to monitor the situation, however at this time it "believes that Pradaxa provides an important health benefit when used as directed and recommends that healthcare professionals who prescribe Pradaxa follow the recommendations in the approved drug label.

Look A-like Sound A-like Medications

Dabigatran Etexilate (Pradaxa) and Argatroban (Argatroban)

are both antithrombotic agents in the category of direct thrombin inhibitors (DTI).



Dabigatran is FDA indicated for the prevention of stroke & systemic embolism in nonvalvular atrial fibrillation as well as for VTE prophylaxis following knee or hip replacement surgery. It is typically dosed **ORALLY** as 75mg or 150mg twice daily.

Argatroban is FDA indicated for therapeutic anticoagulation for the prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation as well as for heparin induced thrombocytopenia. It is typically dosed IV as 2 mcg/kg/minute.

TO PREVENT LOOK ALIKE, SOUND ALIKE MEDICATION ERRORS:

- Separate locations of look alike medications-
- Use look alike sound alike (LASA) auxiliary stickers on bins containing the medication
- Train staff to recognize LASA errors
- For handwritten/oral prescriptions, do not make assumptions; call the prescriber to confirm medication.
- Medication Reconciliation: Check patient's profile & review medication list to prevent errors

14th Annual Patient Safety Congress

(May 23 - 25, 2012)

The National Patient Safety Foundation (NPSF) Annual Patient Safety Congress program committee, had selected Harlem Pharmacy Department, Dr. Ahmad Saleem PhD, RPh to be one of the poster presenter for their 2012 meeting, which was held on May 23-25, 2012 at the Gaylord National in National Harbor, Maryland.

The NPSF had stated they received an overwhelming number of excellent submissions and were pleased to inform Harlem Pharmacy Dept. that our topic would be part of the poster gallery in the Learning & Simulation Center.

The Pharmacy poster was entitled "Medication Errors Monitoring and Management at Harlem Hospital Center" and was well received by the congress participants.

The poster described the computer-based Medication Errors Monitoring System (MEMS) developed by the Pharmacy Department's Assistant Director Farrukh Zaman in collaboration with Pharmacy Clinical Services. The program enables pharmacists to identify drugs that are commonly associated with medication use errors. The MEMS qualitatively and quantitatively analyzes data, generates periodic reports, identifies physicians and nursing units associated with the medication use errors. The MEMS is an effective tool for an inpatient monitoring of medication errors, particularly in identifying prescribing errors.









Pic (above): Dr. Saleem with Jane Hooker (RN, MN, CPHQ, Asst Vice President for Quality, National Association for Public Hospitals).

Pic below (left to right) Dr. Salem with Dr Roberta Locko, Director of Radiology (Harlem Hospital Center) and Dr Uramatsu (MD, PhD, JD, Director Quality and Patient Safety, Tokyo Medical University, Japan).

!!! CONGRATULATIONS !!!







Mrs. Greta Hamer, PAA 3, Office Manager was awarded the Departmental honor for "Caught in the Act" for voluntarily stepping in during Tour III, after completion of her day's work during Tour II, to assist our pharmacy technician after an emergency call out. She stayed throughout the night to ensure pharmacy operations ran smoothly and that patient care was not compromised.

Mrs. Chantele Dupont, pharmacy technician was awarded Departmental Excellence of Service for her hard work, dedication and commitment to the Outpatient Pharmacy. Chantele is a team player and is always accommodative to changes in workflow, making her an invaluable employee.

Touro College of Pharmacy awarded Dr. Farooqi, Assistant Director of Pharmacy (Clinical), the "Preceptor of the Year Award" during their Commencement Banquet held on May 16, 2012. She was recognized for her dedication and devotion to give back and promote the profession of Pharmacy amongst the students. She was also took part in the Hooding Ceremony for the graduating Touro College Pharmacy 2012 Class held on May 17, 2012.



