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Special Points of Interest:

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P&T Update

Formulary Addition/Deletion

- **Daclizumab (Zenapax®)** deletion from the UH Formulary – Approved
- **Hepatitis B Immune Globulin (Hepagam B®)** addition to UH formulary, deletion of NABI-B® – Approved
- **Recombinant Thrombin (Recothrom®)** addition – is a highly specific serine protease that promotes hemostasis by converting fibrinogen to fibrin and acts locally when applied topically to sites of bleed. – Approved
- **Prasugrel (Effient®)** – Prasugrel is a thienopyridine prodrug which inhibits platelet activation by blocking P2Y12 platelet receptor similar to clopidogrel and ticlopidine. It is FDA approved for use to reduce thrombotic events in patients with acute coronary syndromes (ACS) undergoing percutaneous coronary intervention (PCI) including coronary stent. – Approved
- **Lanthanum Carbonate (Fosrenol®)** – is a trivalent cation rare earth element with a high affinity for phosphate, lanthanum is virtually insoluable in water, and only trace amounts are absorbed from the GI tract. – Formulary addition not deemed necessary at this time

The University Hospital American Society of Health-System Pharmacists (ASHP) House of Delegates - Mr. Emont

Congratulations to Mr. Andre Emont upon his 2 year term election by the New Jersey Society of Health-System Pharmacists (NJSHP) to the American Society of Health-System Pharmacists (ASHP) House of Delegates.

Mr. Emont is one of four distinguished hospital based delegates to represent New Jersey in such a capacity. The House of Delegates is the ultimate authority over ASHP professional policies which express the Society's stance on important issues related to health-system pharmacy practice and medication use in society. ASHP's professional policies contain varying level of detail. Policy positions are short pronouncements on one aspect of practice. Statements express basic philosophy, and guidelines (including what were formerly called "technical assistance bulletins") offer programmatic advice.

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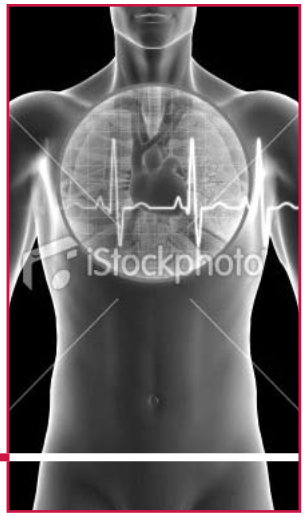
Plavix® (Clopidogrel Bisulfate) and the New FDA Black Box Warning Indication

Plavix® (Clopidogrel Bisulfate) is one of the leading antiplatelet medications in clinical therapy and is currently deemed to be the second best-selling medication in the world. It has reigned supreme in medical use with its primary indication in reducing the risk of heart attack, unstable angina, stroke, and cardiovascular death in patients with history of cardiovascular disease. Plavix® has also been shown to provide significant off-label use on patients with atrial fibrillation, chronic heart failure, and percutaneous coronary intervention. However, with the dawn of Effient® (Prasugrel Hydrochloride), the upcoming brand-generic conversion, and most importantly, the recent FDA Black Box Warning label, it seems that Plavix®'s period of dominance is numbered.



On March 12, 2010, the U.S. Food and Drug Administration (FDA) has added a Black Box Warning label to the prescribing information, describing its reduced effectiveness in patients who are "poor metabolizers" of Plavix®. "Poor metabolizers" are considered to be patients who carry the variant CYP2C19 gene, affecting the ultimate metabolism of the drug to its active form. The new label warns that the normally indicated doses of Plavix® have a potentially dangerous lack of efficacy in 2% to 14% of patients. A definite line cannot be drawn to differentiate the significance of race with this issue due to gene variation, which may make a patient a hypo-, intermediate-, or hyper-responder, which even complicates the appropriate dosing of Plavix®.

Healthcare professionals are advised to educate their patients about this current medication issue and are encouraged to perform tests on suspected "poor metabolizers" to identify any genetic differences in the CYP2C19 function and to modify therapy accordingly. Nevertheless, test results are unreliable and have not been obtained efficiently, increasing the cardiovascular risks of the patients. Time is of the essence; hence, waiting for any clinical effect is not ideal in patients who are at high risk for heart attack, stroke, and even death due to cardiovascular disease. Doubling the normal dose is also suggested but very limited clinical trials support this alternative, not to mention the adverse drug reaction possibilities with the adjusted dose. The use of other antiplatelet medications, like Effient® (Prasugrel Hydrochloride), is being promoted for prophylactic and maintenance care due to its same indication but different mechanism of action.

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The University Hospital American Society of Health-System

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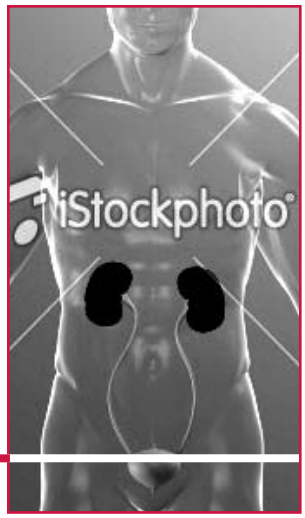
Therapeutic position statements are concise responses to specific therapeutic issues, and therapeutic guidelines are thorough, evidence-based recommendations on drug use. The House of Delegates meets annually at the ASHP Summer Meeting, (this year in Tampa) where it reviews policy proposals that have been approved by the Board of directors; most professional policies are initially drafted by ASHP Councils or the executive committee of sections and forums.

His leadership and dedication to the profession of Pharmacy on all levels demonstrate the strength and quality of Pharmacy leadership in New Jersey as well as nationally.

Respectfully submitted by Michael Chu, Pharm.D.

First Generic Tamsulosin Approved by FDA



Benign Prostatic Hyperplasia (BPH), the enlargement of the prostate, is a common condition affecting older men. According to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a subsidiary of the National Institute of Health (NIH), more than half of men in their sixties develop symptoms of BPH. Common symptoms of BPH include hesitant, interrupted weak stream; urgency and leaking or dribbling; and more frequent urination at night. While the reasons for the development of BPH are still not well understood, there are many medications and procedures available for treating the symptoms of BPH.

Tamsulosin hydrochloride is a part of the class of medications known as alpha blockers, which works by relaxing the smooth muscle of the bladder to increase the flow of urine. Indicated for the treatment of symptoms associated with BPH, Flomax® Capsules (tamsulosin hydrochloride) now have a generic alternative. The FDA has stated that prescribing information and safety warnings for the generic tamsulosin capsules are the same as compared to the Flomax® capsules. The first generic tamsulosin capsules are being manufactured by IMPAX Laboratories Inc. of Hayward, California. At least five more manufacturers are pending approval and subsequent release of generic tamsulosin capsules.

The first generic tamsulosin hydrochloride was approved on March 2, 2010.

Contributed by:
Ted Yang, Pharm.D. Candidate 2010

References:
1. Drugs at FDA: FDA Approved Drug Products. Tamsulosin Hydrochloride. Retrieved from: http: www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm fuseaction=Search.Overview&DrugName=TAMSULOSIN% 20HYDROCHLORIDE. Accessed March 5, 2010.
2. FDA News Release: FDA Approves First Generic Tamsu losin to Treat Enlarged Prostate Gland. Retrieved from: http://www.fda.gov/NewsEvents/Newsroom/Press Announcements/ucm202728.htm. March 2, 2010. Accessed March 4, 2010.
3. FLOMAX® (tamsulosin hydrochloride) [Prescribing Information]. Ridgefield, CT: Boehringer-Ingelheim Pharmaceuticals, Inc.

Plavix® (Clopidogrel Bisulfate) and the New FDA

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The data gathered by the FDA is still unclear, but they stand firm with their decision to impose the boxed warning. The looming risk of a cardiovascular event simply outweighs the unpredictable efficacy of Plavix®. With all of the sudden challenges Plavix® has been tackling, its manufacturers. Bristol-Myers Squibb and Sanofi Aventis, are working hard to resolve the current medication issues. They have been clarifying and confounding the data presented by the FDA and conducting more trials of their own to reassure and preserve the value Plavix® have had these past years and to ultimately keep its blockbuster drug on top of the market.

Contributed by:
Patrick Tim Rocafort, Pharm.D. Candidate 2010

References:
1. FDA Drug Safety Communication: Reduced effectiveness of Plavix (clopidogrel) in patients who are poor metabolizers of the drug. www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforpatientsandProviders/ucm203888.htm#AIHP. March 12, 2010. Accessed March 30, 2010.
2. Plavix (clopidogrel): Reduced effectiveness in patients who are poor metabolizers of the drug. www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm204256.htm. March 12, 2010. Accessed March 30, 2010.
3. New Plavix Warning: Lack of Effect in Many People www.webmd.com/heart-disease/news/20100312/new-plavix-warning-lack-of-effect-in-gene-carriers. March 11, 2010. Accessed March 30, 2010.
4. FDA Adds Boxed Warning To Plavix On Effectiveness online.wsj.com/article/BT-CO-20100312-711642.html?mod=WSJ_latestheadlines. March 12, 2010. Accessed March 30,

New FDA Approvals for Hereditary Angioedema

Hereditary angioedema (HAE) is a rare condition, the prevalence of which is 1 in 30,000 to 50,000 people in the world, this disease only accounts for about 2 % of all angioedema cases. HAE is an autosomal dominant condition caused by the mutations on chromosome 11q, which causes an abnormally low level of the protein, C1-esterase-inhibitor (C1–INH). C1- INH regularly functions in the coagulation pathways and acts as an inhibitor of kallikrein, which is an enzyme involved in many biological systems[1]. Common symptoms associated with HAE, are acute attacks of abdominal pains as well as edema, which is unresponsive to epinephrine, antihistamines or steroids. Patients who go untreated may exhibits acute attacks 2 or 3 times a month.

This past year has brought 2 new therapeutic options. The common treatment plans for HAE patients has been mainly management with narcotics, antiemetics and fluid replacement to mange symptoms. C1 inhibitors have been used for therapy in the past, like Berinert®, which is a human C1 Esterase Inhibitor, which was approved on October 9, 2009; however Berinert® is only specific for the abdominal and facial symptoms of HAE attacks. It is created with human plasma, so it poses the risk of transmitting disease with its use. Kalbitor® was also recently approved by the FDA on December 1, 2009. This drug is classified as a potent, selective and reversible, human plasma kallikrein inhibitor. It is used to treat patients 16 years and older with an acute attack of hereditary angioedema.

Some of the most commonly occurring adverse reactions in both medications include headache, nausea, and diarrhea. However the most serious consequence seen with Kalbitor® is the potential to cause anaphylaxis. While with Berinert®, a potential increase in the pain associated with HAE has posed a serious risk.

Nonetheless, it has been an advantageous year for the HAE community, with these new therapies for this rare disease.

Contributed by:
Tamara C. Moise, Pharm.D. Candidate 2010

References:
1. Kalbitor [package insert].Cambridge, MA: Dyax Corp; 2009.[1]
2. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; 2009.
3. About HAE. (2010). Hereditary Angioedema. Retrieved March 8, 2010, from http://www.allabouthae.com/hcp_default.aspx.
4. Zuraw BL. Hereditary Angioedema. New England Journal of Medicine. 2008 Sep 4; 359(10):1027-36.

2009 UH Formulary Addition/Deletion List

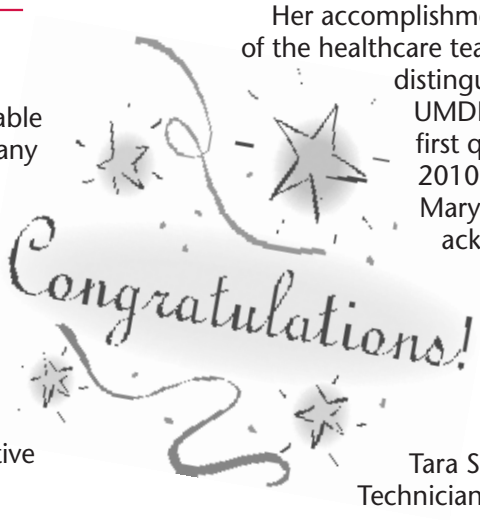
Generic	Brand	Date	Approved	Denied	Deleted	Reason
Propoxyphene-Acetaminophen		2/18/2009			X	Removed from the market because of lack of efficacy and increased incidence of side effects
Neutra-Phos K Powder Packet		2/18/2009			X	Manufacturer discontinue
Metaproterenol Inhaler	Alupent®	2/18/2009			X	Manufacturer discontinued
Edetate Disodium	Endrate®	2/18/2009			X	Manufacturer discontinued
C1 Esterase Inhibitor	Cinryze®	4/16/2009		X		Not deemed necessary at this time
Sitagliptin	Januvia®	5/20/2009		X		Not deemed necessary at this time
Leuprolide	Viadur®	7/15/2009			X	Manufacturer discontinued
Detemir	Levemir®	9/16/2009		X		Not deemed necessary at this time
Albuterol 2.5mg/ Ipratropium 0.5mg/3mL	DuoNeb®	9/16/2009	X			
Potassium Chloride	MicroK®	9/16/2009			X	
Daclizumbad	Zenapax®	10/21/2009				
Hepatitis B Immune Globulin	HepaGam-B®	10/21/2009	X			
Hepatitis B Immune Globulin	Nabi-B®	10/21/2009			X	
Prasugrel	Effient®	12/16/2009	X			
Recombinant Thrombin	Recothrom®	12/16/2009	X			
Lanthanum Carbonate	Fosrenol®	12/16/2009		X		

Employee of the 1st Quarter

Mary Soliman

With her outstanding work ethic and amiable personality, Mary Soliman is regarded by many of her colleagues as one of the most proficient and pleasant pharmacists in the department.

During her first year at the University Hospital, Mary Soliman has merited a five-star nomination for her work performance and was even acclaimed to do "the work of five pharmacists at the same time". Her efforts to provide the most effective and efficient patient care are invaluable and continues on today with her dedication and commitment to her profession. In addition, her co-workers praise her approachable personal, which creates an easy-going environment for everyone to work well in, with less stress and more support for each other.



Her accomplishments as an important member of the healthcare team have earned her the distinguished recognition as UMDNJ-Pharmacy Department's first quarter Essential Piece of 2010. We are very proud to have Mary Soliman in our team and acknowledge her exceptional work not only for the department but for the University Hospital as well.

Congratulations, Mary!

Respectfully submitted by
Tara Shaw, Lead Pharmacy Technician

Policies & Procedures Update

- Lorazepam, midazolam, fentanyl and morphine continuous infusion expansion to all nursing units in palliative care patients only – Approved
- Hypertonic saline 23.4% is restricted to critical care, PACU and ED-Critical Care – Approved
- Erythropoietic/iron outpatient orderset – Approved
- Antiemetic – supportive therapy order revision – Approved
- National Patient Safety Goal – Heparin-induced thrombocytopenia guideline – Approved
- Thrombin Bovine JMI product deletion from the UH formulary. Pharmacy will only stock Recothrom® – Approved
- Updated restricted antibiotic policy with the following changes:

1. Use of term "anti-infective" instead of "antibiotic"
2. Restriction of intravitreal/intraocular/topical eye drops for amphotericin B, cidofovir, foscarnet, voriconazole will require Ophthalmology approval
3. Addition of polymyxin B to the restricted antibiotic list, default duration of approval for any restricted antibiotic will be 7 days unless specified otherwise by the physician – Approved
4. Oxacillin and Bicillin CR deletion from the UH formulary – Approved
5. Timentin® (Ticarcillin-Clavunate) deletion from the UH formulary – Approved