

# PHARMACY NEWSLETTER

Vol. V, Issue 5

A PUBLICATION OF THE DEPARTMENT OF  
PHARMACEUTICAL CARE

SEPTEMBER-OCTOBER 2008

## Special Points of Interest:

- *P&T Update*
- *Policy and Procedure / Guideline*
- *Patient Safety*
- *Clinical Safety / PI Change news*

## P&T UPDATE

### Formulary Addition/Deletion

#### Micafungin Sodium (Micamine®)

Antibiotic Subcommittee minutes – Micafungin formulary addition request was reviewed and deemed not necessary at this time.

#### Paliperidone (Invega®) –addition-approved

Paliperidone is an extended-release formulation for treatment of schizophrenia. It is the primary active metabolite of risperidone (Risperdal®) which is to become generic this month. Formulary reviewer discussed the studies provided on paliperidone. The trial compares placebo. The favorable result from these studies can not be used to assess superiority/ inferiority to other second generation antipsychotics. The Medical Letter concluded no specific advantages have been demonstrated & it is likely to be similar to risperidone in effectiveness & adverse effect. The route of metabolism, the elimination via urine & the sedative side effect were cited as major advantages. Approximately 60% of psychiatric patients will be converted to Paliperidone. A suggestion to restrict to psychiatric unit was returned with recommendation to have paliperidone available to the whole institution. The generic version of risperidone will likely cost pennies to dimes versus paliperidone costs \$ 15.19/day

#### Trasylol (Aprotinin®) deletion- approved

Fibrinolytic inhibitors have been widely used in patients undergoing elective coronary artery interventions. A proposal to delete trasylol from UH formulary was agreed upon by CT surgeons on staff



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## Policy and Procedure Update

### Medication order stop time policy update:

All orders for ondansetron are good for 48hrs  
– Approved

### Nursing – Pharmacy Committee Minutes:

All orders for look alike/sound alike medications are to be checked by two registered nurses before administration to the patients. It will be documented as double signature of the RNs in the MAR. – Approved

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### Transcription of Med order/adm/ std. med schedule P&P revision

Revision of the policy presented.

Key change includes “statins” standard administer time at bedtime (22:00)

“Daily” to be scheduled as 10:00

Once daily dispensing from pharmacy to 13:00, any orders past 13:00 will be scheduled to administered the next day at 10:00

### Medication sample P&P – Revision-approved

The sample medication additions-  
Cardiology ACC clinic: Losartan 50mg & 100mg addition  
Ophthalmology DOC 6100: Loteprednol 0.5%/tobramycin 0.3%, Nerafenac 0.1%, Prednisolone 1%

**Tiotropium (marketed as Spiriva Handi-Haler)** FDA informed healthcare professionals that FDA has reviewed preliminary data from UPLIFT (Understanding the Potential Long-Term Impacts on Function with Tiotropium), a large, 4-year, placebo controlled clinical trial with Spiriva HandiHaler in approximately 6000 patients with chronic obstructive pulmonary disease. The preliminary results reported by Boehringer Ingelheim to the FDA showed that there was no increased risk of stroke with tiotropium bromide compared to placebo. Two recent publications reported increased risk for mortality and/or cardiovascular events in patients who received tiotropium or inhaled anticholinergics. Both studies examined cardiovascular outcomes. FDA expects to receive the complete report for UPLIFT in November 2008. Results from this trial will also help to address some issues raised about tiotropium in the two recent publications. Due to the amount of data collected in UPLIFT, a complete review of the results could take several months, at which time FDA will update this communication with the final results of the UPLIFT analysis, as well as all the available data regarding tiotropium and stroke risk. Ref:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Tiotropium>



## **FDA Clinical/Medwatch/patient safety alerts/ black box warnings**

### **Mycophenolate and progressive multifocal leukoencephalopathy ( PML)**

Based on the postmarketing data, cases of progressive multifocal leukoencephalopathy have been reported in patients treated with mycophenolate. Hemiparesis, apathy, confusion, cognitive deficiencies, and ataxia were the most frequent clinical features observed.



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Both conventional and atypical antipsychotics are associated with an increase risk of mortality in elderly patients treated for dementia related psychosis. Analysis of 17 placebo controlled trials that enrolled 5377 elderly patients with dementia related behavioral disorders revealed a risk of death in drug treated patients of between 1.6 to 1.7 times that seen in placebo treated patients. Most deaths appeared to be either cardiovascular or infectious in nature.

### **Fluroquinolones and tendonitis/tendon rupture**

Based on increased reports of tendinitis and tendon rupture with fluroquinolones antibiotics, FDA has asked the manufacturers to include a boxed warning in the package insert indicating the increased risk of tendonitis and tendon rupture while on these antibiotics. This risk is further increased in those over age 60, in kidney, heart, and lung transplant recipients, and with use of concomitant steroid therapy. Physicians should advise patients at the first sign of tendon pain, swelling or inflammation, to stop taking the fluroquinolone, to avoid exercise and use of the affected area and to promptly contact their doctor about changing to non fluroquinolone antimicrobial.

### **Raptiva (efalizumab)**

FDA notified healthcare professionals of extensive labeling changes, including a Boxed Warning, to highlight the risks of life-threatening infections, including bacterial sepsis, viral meningitis, invasive fungal disease, progressive multifocal leukoencephalopathy and other opportunistic infections with the use of Raptiva. In addition, the prescribing information will be updated to describe a potential risk for the permanent suppression of the immune system with repeat administration of Raptiva in children. Raptiva is not approved for children under 18 years of age. Doctors and other prescribers should carefully evaluate and weigh the risk/benefit profile of Raptiva for patients who would be more susceptible to these risks. Health care professionals should monitor patients treated with Raptiva for the signs and symptoms of these adverse events and also instruct patients to report any such signs and symptoms to them without delay. Patients identified to begin therapy with Raptiva should have received all their age-appropriate vaccinations before starting the drug. Patients with pre-existing infections or who have a compromised immune system should notify their health care professional before beginning treatment with Raptiva. Ref: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Raptiva>

**ISMP Reports Increasing Drug-Related Injuries**  
**Gener Eric Cruz**  
**Pharm. D. Candidate 2009**

Reports reveal a substantial increase in drug-related injuries and deaths in the first quarter of the year, with 4825 deaths and nearly 21,000 injuries. The Institute for Safe Medication Practices or ISMP, whose reports are based on side effects voluntarily submitted to the FDA, declared that these injuries and deaths rose nearly three times from the previous quarter. Further, there is a 38% increase in injuries from last year's quarterly average. The increase in adverse effects has been linked with at least ten drugs, each causing more than 100 deaths, with a significant number of them has been linked with the use of narcotic analgesics, heparin and Chantix.

**New Update:** The FDA plans to add more warnings to Chantix because of increasing reports of road traffic accidents and seizures. Many federal agencies have prohibited many of their employees from using this drug. Currently, there is no evidence that Chantix causes these problems.

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**Controversial Issue: Requirement for Female Immigrants-** Even though Gardasil is only recommended for U.S. residents, female immigrants between the age of 11-26 are required to receive this vaccine as of August 1, 2008. Safety and cost are the major concerns.

## So What's New?

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**Pharm. D. Candidate 2009**



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