Family Medicine Clinical Pharmacy Forum
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Family Medicine Clinical Pharmacy Forum is a brief bi-monthly publication from the Family Medicine clinical pharmacists distributed to faculty and residents of the Department of Family Medicine. Our intent is to provide timely information on broad-based issues of pharmacotherapy, as well as regulatory and practiced-based issues affecting you as a prescriber. If you have suggestions for things you would like to see in the newsletter, please contact one of us.

Pharmacotherapy Issues.

New Drug. Boniva™ (ibandronate) is a new intermittently-dosed bisphosphonate for the prevention and treatment of osteoporosis. It is unique from the other bisphosphonates in that it is given orally once every month (150mg once a month). Boniva™ 150mg tablet costs around $76/month, while Fosamax™ and Actonel™ cost around $65/month. A support group called My BONIVA has been formed to help with compliance for this once a month medication. Patients can enroll by contacting either 1-800-4BONIVA or www.mybonvia.com

New Drug. Lunesta™ (eszopiclone) is a new, non-benzodiazepine sleeping aid. It is in the same class as to zolpidem (Ambien™) and zaleplon (Sonata™) and is considered a “me too” drug. It is different from the other drugs in its class as it is not limited to short term use. It is approved for treatment of insomnia (2 – 3 mg at bedtime) up to 6 months in duration. Lunesta™ has a half life of 4 to 6 hours and common side effects include sedation, dizziness, confusion and headaches. It is available in 1, 2, and 3mg tablets and costs around $100.00 for 30 tablets. Ambien™ (10mg at bedtime) costs around $88.00 for 30 tablets and generic trazodone (50mg at bedtime) costs significantly less at around $8.00 for 30 tablets.

New Drug. Xifaxan™ (rifaximin) is a derivative of rifampin that has received FDA approval for traveler’s diarrhea caused by noninvasive strains of Escherichia coli. Unlike rifampin, <0.4% of Xifaxan is absorbed from the GI tract. Side effects included headache, constipation, vomiting, and flatulence. A disadvantage with Xifaxan is that it is dosed at 200mg TID for 3 days. Levaquin is dosed at 500mg/daily and Cipro is dosed at 500mg BID. All three treatments are similar in price.

“Medical Foods.” Limbrel™ (flavocoxib) is a new product being advertised as a “medical food” for osteoarthritis. It contains a combination of plant flavonoids. Medical foods are allowed to make claims for treating a medical condition, whereas dietary supplements can only make structure and function claims. However, it costs about $90/month and there is no evidence to support its use. For more information about this new marketing gimmick, see the May 2005 Prescriber’s Letter.

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Regulatory Issues.

Drug Withdrawal. After concluding that the overall risk versus benefit profile is unfavorable, FDA has requested Pfizer, Inc. to voluntarily withdraw Bextra™ (valdecoxib) from the market. For more information, see: http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Bextra
Contrary to rumors, there are NO immediate plans to bring Vioxx™ back on the market. It is true that the FDA subcommittee voted that it *could* be brought back (with stricter labeling), but Merck has not announced any official plans.

Pseudoephedrine. Effective 5/21/05, most pseudoephedrine-containing products sold in Iowa will be handled as Schedule V controlled substances. This new law affects pseudoephedrine provided as a single-agent product and any combination product that contains any amount of pseudoephedrine. As with other controlled substances, these products must be stored within pharmacy and all patient care areas under lock and key, and a perpetual inventory of supplies kept on hand must be maintained. Outpatient prescriptions for any pseudoephedrine-containing products will also be treated like other controlled substances in Schedules III, IV and V; the prescriber must supply his/her DEA registration number on the prescription and the number of refills will be limited to five (or six months). The new law limits the amount that can be purchased without a prescription to 7500 mg (total) within a 30-day period. Purchasers must be 18 years of age and provide a government-issued photo ID (e.g., a driver’s license).

Reminyl™ (galantamine), for Alzheimer’s disease, has been renamed Razadyne™.

Multiple C-II Rx’s. Apparently the new DEA interpretation of not allowing multiple C-II Rx’s to be written on the same day (with instructions to not fill until a certain date) is causing a big uproar. The actual law has not changed, only the DEA interpretation. Many state boards say that it is still legal to do so. I called the Iowa Board of Pharmacy Examiners for clarification, and they told me that you can only write a future fill date on one C-II Rx and it should be within a 15-day window of when to fill it. In other words, if you see a patient for a visit and notice that they will run out of their C-II in a few days, you can write a new Rx (with today’s date) and instruct that it not be filled until a certain date (the Board recommends this be within a 15 day window). You should continue to rewrite C-II Rx’s on a monthly basis and not post-date or provide multiple Rx’s with future fill dates. The Board advises me that the DEA may be revisiting this later.

Research.

Enrollment continues in the Collaborative Management of Hypertension Study. If you have a newly diagnosed hypertensive patient or a patient on treatment and not at BP
goal, please have one of the nurses contact Karen Kluesner at 430-7335. Fliers are posted in the patient care areas.

**Clinical Pearl.**

A recent drug information question I received was: “Does androstenedione affect testosterone levels?”

Yes, oral androstenedione supplementation has been shown to down-regulate endogenous testosterone production through its reduction in circulating LH levels and subsequent increases in estrone and estradiol levels. In the Andro project, 15 men (mean age 43) receiving androstenedione 100 mg BID were found to have testosterone levels that decreased 16% after 1 month of use. Enhancements in adaptation to resistance training were no different than placebo for body composition or muscular strength.