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, please contact us.

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Generic Drugs

Generic drugs – saving money is a good thing!

Currently, over 50% of prescriptions are filled with generic drugs that average $50-$60 less than brand name drugs and save the public and their insurance companies over $20 billion per year. Most patients and insurance companies, however, would like those numbers to be even higher.

Here are a few of the newest generics to come to market along with the price comparison to their brand name counterparts. Keep in mind that one generic company will have exclusive rights to the generic patent for 6 months, therefore, the prices for the generics will be higher at first until other generic companies are allowed to compete and drive the prices down.

<table>
<thead>
<tr>
<th>Qty</th>
<th>Brand Name</th>
<th>Price</th>
<th>Generic Name</th>
<th>Price</th>
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</thead>
<tbody>
<tr>
<td>30</td>
<td>Lotrel 2.5/10mg</td>
<td>$74.40</td>
<td>Amlodipine/Benazapril</td>
<td>$73.99</td>
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<td>30</td>
<td>Norvase 5mg</td>
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<td>Amlodipine</td>
<td>$46.99</td>
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This issue authored by:
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What’s next? Here is the anticipated availability of first-time generics and/or patent expiration dates for the rest of 2007. Don’t forget, however, that patent expiration and generic availability are complicated by legal maneuvers on both sides and the ultimate release date on all of these products is TBD.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Manufacturer</th>
<th>Anticipated Availability</th>
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<tbody>
<tr>
<td>Imitrex</td>
<td>Sumatriptan</td>
<td>GlaxoSmithKline</td>
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</tr>
<tr>
<td>Lamisil</td>
<td>Terbinafine</td>
<td>Novartis</td>
<td>June</td>
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<tr>
<td>Cerebyx</td>
<td>Fosphenytoin</td>
<td>Parke-Davis</td>
<td>August</td>
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<tr>
<td>Exelon</td>
<td>Rivastigmine</td>
<td>Novartis</td>
<td>August</td>
</tr>
<tr>
<td>Geodon</td>
<td>Ziprasidone</td>
<td>Pfizer</td>
<td>September</td>
</tr>
<tr>
<td>Coreg</td>
<td>Carvedilol</td>
<td>GlaxoSmithKline</td>
<td>September</td>
</tr>
<tr>
<td>Toprol XL</td>
<td>Metoprolol succinate</td>
<td>AstraZeneca</td>
<td>November</td>
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<tr>
<td>Meridia</td>
<td>Sibutramine</td>
<td>Abbott</td>
<td>December</td>
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<tr>
<td>Movik</td>
<td>Trandolapril</td>
<td>Abbott</td>
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<tr>
<td>Kytril</td>
<td>Granisetron</td>
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<td>Janssen</td>
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<td>Zyrtec</td>
<td>Cetirizine</td>
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**Simvastatin use associated with lower risk of dementia and Parkinson’s Disease?**

According to a recent study headed by Dr. Benjamin Wolozin at the Boston Universtiy School of Medicine, simvastatin use was associated with a 50% lower incidence of dementia and Parkinson’s Disease.
Elestrin – a new estradiol gel for menopausal vasomotor symptoms

Elestrin is an estradiol gel indicated for treatment of moderate to severe vasomotor symptoms associated with menopause. Elestrin is a hydroalcoholic gel for transdermal application supplied in a pump formulation. The recommended dose is one pump, which is equivalent to 0.52mg estradiol. The recommended application site is the upper arm and shoulder, but it may also be applied to the thighs or abdomen. With one or two pumps, Elestrin gel systemically delivers 0.0125mg and 0.0375mg of estradiol, respectively. In comparison, estradiol patches like Climara release between 0.025 and 0.1mg estradiol per patch. In clinical trials, two pumps of Elestrin daily produced statistically significant reductions in number and severity of hot flashes compared to placebo by the fourth week. One pump daily produced similar results by week 5. [Simon JA, Bouchard C, Waldbaum A, Utian W, et al. Low dose of transdermal estradiol gel for the treatment of symptomatic postmenopausal women. Obstet Gynecol. 2007; (109)3:588-96.]

Common side effects include breast tenderness (9%), metrorrhagia (6%), nasopharyngitis (14%), and URI (8%). Other side effects include nausea, increased blood pressure, hypothyroidism, photosensitivity, and fluid retention. As Elestrin is an estrogen product, similar contraindications exist that are present with other estrogen formulations, including increased risks of endometrial cancer, cardiovascular disease, and blood clots. Sunscreen should not be applied before use or until 30 minutes after Elestrin application, as it increases the absorption of Elestrin. Retail cost for Elestrin runs $134.99 for one tube, while EstroGel, a similar product approved in 2004, runs $99.37 for a 93 gram tube. A one month supply (15ml) of an estradiol cream similar in strength to both products costs $33.73 through a local compounding pharmacy (NuCara), so you may save money if you check with your local pharmacist first.
Vitamin E – An Update

Many people continue to take Vitamin E supplements in the belief that it will prevent various chronic diseases. Vitamin E is the most widely used vitamin in the U.S., with 22% of adults greater than 55 years of age reporting daily use. However, recent studies have reported no benefit, and the possibility for harm with “high” dose (≥400 IU/day) Vitamin E use.

A 2005 meta-analysis (Ann Intern Med 2005;142:37-46) of Vitamin E use reported a significant dose-dependent relationship between vitamin E use and all-cause mortality (RR 1.04 (1.01-1.07) for dosages ≥400 IU daily). Mortality increased for dosages >150 IU/day. The authors felt that use of Vitamin E supplements should be discouraged pending proof of efficacy.

The 2005 report from the Women’s Health Study (JAMA 2005;294:56-65) reported no effect of Vitamin E 600 IU every other day on preventing major cardiovascular events or total mortality in women. However, they did note a significant 22% reduction in cardiovascular mortality, largely attributable to fewer sudden deaths. The researchers felt their data do not support recommending Vitamin E supplementation for cardiovascular disease or cancer prevention.

Most recently, another meta-analysis of primary and secondary prevention trials (JAMA 2007;297:842-57) observed a small, but significant, 4% increase in total mortality with Vitamin E supplement use.

Considering these recent studies, it seems the message to patients should be that Vitamin E won’t help for cardiovascular disease prevention, and may even be associated with some increased risks.

New Dietary Supplement Promoted to Pregnant and Nursing Moms

Expecta Lipil DHA, by Mead Johnson, is a new 200mg capsule dietary supplement for pregnant and nursing moms. Expecta Lipil DHA is a docosahexaenoic acid (DHA) supplement to be taken once daily throughout pregnancy and nursing. DHA is an omega-3 fatty acid found primarily in seafood that has been associated with improved brain, nervous system, and retinal fetal development and function. Animal studies have shown that DHA promotes the development of hippocampal neurons in vitro by increasing neurite extension and branching\(^2\). As it has been long recommended for pregnant women to avoid seafood products due to a higher risk of mercury toxicity, the advent of a safer alternative to obtain DHA is appealing. One long-term observational study in England showed that maternal consumption of 340mg per week of DHA-containing seafood actually provided beneficial effects on child development via measurement of intelligence quotient tests.\(^1\) Expecta is made from a non–fish source derived from

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Crypthecodinium cohnii oil, which contains the only DHA source that is accepted as Generally Recognized as Safe (GRAS) for use in infant formula. (Food and Drug Administration. Agency Response Letter. GRAS Notice Nos. GRN000041. 05–27–2001 and GRN000080. 12–11–2001.)

There is little primary literature available to support the use of this product in the pregnant and nursing population. There are no guidelines set by the FDA or the American College of Obstetrics and Gynecology regarding daily intake of DHA. However, a panel of experts on lipid nutrition (ISSFAL) has recommended DHA intake of 300mg per day for pregnant and nursing mothers. The manufacturer does not recommend a specific start time for Expecta, but they do point to studies that show DHA is most important to baby’s growth in the third trimester through 18 months.

A randomized trial (N=291) of pregnant women taking 33-133 grams of DHA (through egg intake) during the 3rd trimester showed increased gestational duration (6 days ± 2.3 days) which may improve fetal growth³. No safety concerns were noted from this study.


Zelnorm – it’s back….but via restricted use

Novartis removed Zelnorm (tegaserod maleate) from the market in March 2007 when a new safety analysis (involving over 18,000 patients) identified it was associated with a higher risk of MI, stroke, and unstable angina compared to placebo. Zelnorm is a prescription drug approved for short term treatment of women with irritable bowel syndrome with constipation and for patients younger than 65 years with chronic constipation.

Just recently, the FDA announced it is allowing the restricted use of Zelnorm under a treatment IND protocol to treat women with irritable bowel syndrome with constipation and chronic idiopathic constipation in women younger than 55 who meet specific guidelines. Patients must have no known or pre-existing heart problems. Patients will have to sign an informed consent form prior to receiving the drug.

Physicians who have patients that may be interested should contact Novartis at 888-669-6682 or 866-248-1348.
SMOKING CESSATION GROUP CLINIC

The Smoking Cessation Group Clinic continues to be available to assist patients in smoking cessation. A clinical pharmacist leads the clinic to provide a well-rounded approach to help people stop smoking. The next two clinics start on September 11th and November 6th.

- Each group consists of six sessions held over the period of eight weeks.
- Each session will meet over the noon hour on Tuesdays.
- There is currently no charge to participate.
- Sessions are held in Counseling and Health Promotion Services in the Family Care Center.
- To participate in this clinic, the patient must be older than 18, smoke daily, and be willing to quit smoking within the first 30 days of the clinic.

To request this service, an electronic consult form is available in IPR as an e-Order. The order is titled: Smoking Cessation Group Clinic Consult and can be found in the FCC Family Practice and Master folders.

Questions may be directed to Ann Philbrick at 6-4712 or 5527.