P.R.N.

ISSN # 1941-9481

www.prnnewsletter.com

Volume 4, Number 6 | **A Monthly Newsletter for Community Pharmacists** | **June, 2010**

What's Inside…

FDA NEWS

New Warning Label on Long-Acting Beta Agonists

The FDA will now require manufacturers to include new warnings on the labels of long-acting beta agonists (LABAs). This action was taken as a result of an FDA analysis which showed an increased risk of severe exacerbation of asthma symptoms, leading to hospitalizations, in pediatric and adult patients, as well as deaths in some patients using LABAs for the treatment of asthma. The new labels will include the following recommendations:

- **Use of single-agent LABAs is *contraindicated* without the use of a controller medication (e.g., inhaled steroid)**
- **LABAs should not be used in patients whose asthma is adequately controlled on inhaled corticosteroids**
- **Once asthma control is achieved and maintained, LABAs should be discontinued if possible**
- **Pediatric and adolescent patients who require addition of a LABA should use a combination product**

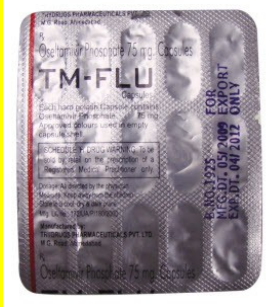
……RX NEWS……RX NEWS……RX NEWS……RX NEWS……

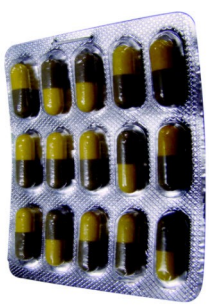
BPH Combination Approved: The FDA has approved a new fixed-dose combination drug for the treatment of symptomatic benign prostatic hyperplasia (BPH). GlaxoSmithKline's **Jalyn** contains 0.5 mg of the 5 alpha-reductase inhibitor dutasteride (**Avodart**) and 0.4 mg of the alpha$_1$ blocker tamsulosin (**Flomax**). Patients should be advised that orthostatic hypotension or syncope can occur with Jalyn, that Jalyn may interfere with cataract surgery, and not to donate blood until 6 months after their last dose. Women who are pregnant or who may become pregnant should not handle Jalyn capsules. In clinical trials, the most common adverse reactions included ejaculation disorders, impotence, decreased libido, dizziness, and breast disorders. Due to the tamsulosin component of Jalyn, use caution in patients with sulfonamide allergy. Jalyn is metabolized by both CYP3A4 and CYP2D6, and use with known inhibitors of these enzymes can lead to increased blood levels and side effects. Use of Jalyn with **ketoconazole** and **paroxetine** is not recommended. Caution should be exercised when using Jalyn with less potent inhibitors as well, including **erythromycin** and **terbinafine**. Jalyn should be used with caution in patients taking PDE-5 inhibitors (**Cialis**, **Levitra**, **Viagra**) as the combination may increase the risk of hypotension. The recommended dose of Jalyn is 1 capsule daily, approximately 30 minutes after the same meal each day. Jalyn capsules should be swallowed whole, and not crushed, chewed, or opened.[1]

New LABA/Steroid Combination: Merck is introducing a newly-approved combination inhaler called **Dulera** for the treatment of asthma in patients 12 years of age and older. Dulera consists of the corticosteroid mometasone (**Asmanex**) and the long-acting beta agonist (LABA) formoterol (**Foradil**). The product labeling for Dulera will contain a **black box warning** stating that LABAs may increase the risk of asthma-related death, as well as the new guidelines for use of LABAs (see ***FDA NEWS*** on this page). Dulera is not indicated for the relief of acute bronchospasm and should not be initiated in acutely deteriorating asthma. In clinical trials, the most common adverse reactions were nasopharyngitis, sinusitis, and headache. Dulera should be used with extreme caution in patients using MAO inhibitors, tricyclic antidepressants, and drugs that prolong the QTc interval. Dulera will be available in two strengths of mometasone/formoterol: 100 mcg/5 mcg and 200 mcg/5 mcg. The recommended dose of Dulera is 2 inhalations twice daily of either the 100/5 or 200/5 strength (start with the higher dose in patients whose previous therapy included inhaled high dose corticosteroids). Patients should be instructed to prime the inhaler before first use by releasing 4 puffs into the air, shaking the inhaler well before each actuation. If the inhaler is not used for more than 5 days, it must be primed again. Tell patients to shake the inhaler well before each use and to wait at least 30 seconds between the first and second puff. Also remind them to rinse their mouth with water after using the second puff to prevent thrush.[2]

FDA Warns Consumers of Sale of Fraudulent Tamiflu

The U.S. Food and Drug Administration is warning consumers about a potentially harmful product being sold over the Internet, advertised as "Generic Tamiflu." The FDA was able to purchase the product, without a prescription, from an online drugstore. The product was received in an envelope postmarked from India, and consisted of two foil-backed blister packs each with 15 yellow and tan capsules containing white powder. Testing of the contents of the capsules revealed that they actually contained **cloxacillin**, a penicillinase-resistant penicillin. Since the product does not contain **oseltamivir**, the active ingredient in Tamiflu, it will have no efficacy in treating influenza and, additionally, can expose penicillin-allergic patients to a potentially life-threatening anaphylactic reaction. FDA Commissioner Dr. Margaret A. Hamburg released the following statement: "Medicines purchased from websites operating outside the law put consumers at increased risk due to a higher potential that the products will be counterfeit, impure, contaminated, or have too little or too much of the active ingredient."





MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Preferred Drug Program Update

The New York state Department of Health has announced the following changes to the Preferred Drug Program (PDP), effective June 17, 2010. The following agents will now be covered under the PDP:

New Preferred Agents

Angiotensin Receptor Blockers:

Valturna

ARBs + Diuretics:

Exforge HCT

Proton Pump Inhibitors:

Omeprazole Rx

The following agents will now require prior authorization:

New Non-Preferred Agents

Angiotensin Receptor Blockers:

Avapro
Benicar

ARBs + Diuretics:

Avalide
Benicar HCT

HMG-CoA Reductase Inhibitors:

Lescol
Lescol XL

Proton Pump Inhibitors:

Prevacid Rx
Prevacid OTC

In addition, the following agents *will no longer require* prior authorization through the Clinical Drug review Program:

Byetta
Victoza

Vacation Supply Discontinued

Effective July 15, 2010, Submission Clarification Code "03" (Vacation Supply) will no longer be acceptable as an override for Early Fill rejections. In extenuating circumstances, beneficiaries should call (518) 496-3209 at least seven days prior to departure.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

The New York State EPIC Program

The New York State Elderly Pharmaceutical Insurance Coverage Program (EPIC) was established under Chapter 913 of the Laws of 1986 and implemented in 1987 (see Title 3 of the New York State Elder Law). Since that time there have been a number of changes to the program, most recently those dealing with the advent of the Medicare Part D Prescription Drug Program. This month, the Law Review looks at the key provisions of the program.

Eligibility and Program Types

New York State residents aged 65 years or older with incomes under $35,000 for singles and $50,000 for couples are eligible for enrollment into the EPIC program. There are 2 enrollment plans available: the FEE plan and the DEDUCTIBLE plan. The FEE plan is available for singles with an annual income of $20,000 or less and couples with an annual income of $26,000 or less. FEE plan participants are responsible for a once-yearly fee, ranging between $8 and $300 depending upon income and marital status, after which they pay only a co-pay. Those enrolled in the DEDUCTIBLE plan must pay for their prescriptions until they reach their deductible, which ranges between $530 and $1715, depending upon income and marital status, after which they pay only a co-pay.

Co-Pay Structure and Plan Limitations

The EPIC co-payment varies with the cost of the drug and/or the amount of the Medicare D co-payment submitted to EPIC, according to the following schedule:

Prescription Cost	EPIC Co-Pay
Up to $15.00	**$3.00**
$15.01 - $35.00	**$7.00**
$35.01 - $55.00	**$15.00**
$55.01 and over	**$20.00**

EPIC covers up to 100 tablets or capsules, or a 30-day supply, whichever is *greater*. Up to a 30-day supply is covered for products other than tablets and capsules (liquids, patches, inhalers, creams, injectables). If an EPIC recipient has Medicare D coverage, the *Medicare plan limits must be followed*.

EPIC and Medicare Part D

EPIC enrollees who are eligible for the Medicare Part D Prescription Drug Program *must* use Medicare as their primary prescription insurance. Pharmacists should bill EPIC only after first billing Medicare Part D. When billing both Medicare Part D and EPIC, pharmacists should adhere to the primary plan (Part D) quantity limits, and bill EPIC only after correcting the quantity to the plan limit. If a particular drug is rejected by Part D or any other primary plan because it is non-formulary or requires prior authorization, the pharmacist must contact the prescriber before billing the prescription to EPIC. This action will result in one of three possible outcomes:

1. **The prescriber changes the drug to one that is covered. Bill the primary plan, then bill the co-payment or deductible to EPIC with an Other Coverage Code (OCC) of 8.**
2. **The prescriber does not agree to change the drug. Bill the claim to EPIC with the Other Payer Reject Code, an OCC of 3, and a Submission Clarification Code (SCC) of 7. The prescriber need not be consulted again when refilling the prescription, but must be contacted whenever a new prescription is presented.**
3. **The prescriber could not be reached. Bill the claim to EPIC with the Other Payer Reject Code, an OCC of 3, and an SCC of 99, certifying an attempt to contact the prescriber was made. The pharmacist must attempt to contact the physician again prior to any refilling of the prescription.**

Feature Article..

OPHTHALMIC DROPS FOR ALLERGIC CONJUNCTIVITIS

Summertime and the livin' is easy, or so messrs Gershwin and Heywood would have you believe. Not true for allergy sufferers, as the season drags on and on. One of the most ubiquitous, and annoying, symptoms being allergic conjunctivitis, we thought it might be a good time to review the current selection of prescription products available for the treatment of itchy, watery, red eyes. As with all ophthalmic drops, patients should be counseled as follows: Do not let tip of applicator touch eyes. Do not contaminate tip of applicator (may cause eye infection, eye damage, or vision loss). Do not use these products to treat contact lens irritation. Counseling points specific to the products discussed here appear in the charts below

Antihistamine Ophthalmic Drops

Product (active)	Generic?	Pediatric Dose	Adult Dose	Counseling Points
Emadine (emedastine)	No	≥ 3 yo: 1 drop in affected eye up to 4 times a day	1 drop in affected eye up to 4 times a day	Remove contact lenses before use and do not reinsert if eyes are red

Antihistamine/Mast Cell Stabilizer Ophthalmic Drops

Product (active)	Generic?	Pediatric Dose	Adult Dose	Counseling Points
Bepreve (bepotastine)	No	≥ 2 yo: 1 drop in affected eye(s) twice daily	1 drop in affected eye(s) twice daily	Remove contact lenses before use and do not reinsert if eyes are red
Elestat (epinastine)	No	≥ 3 yo: 1 drop in each eye twice daily	1 drop in each eye twice daily	Same as above
Optivar (azelastine)	Yes	≥ 3 yo: 1 drop in affected eye(s) twice daily	1 drop in affected eye(s) twice daily	Same as above
Pataday (olopatadine)	No	≥ 3 yo: 1 drop in affected eye(s) once daily	1 drop in affected eye(s) once daily	Same as above
Patanol (olopatadine)	No	≥ 3 yo: 1 drop in affected eye(s) twice daily	1 drop in affected eye(s) twice daily	Same as above
Zaditor (ketotoifen)*	Yes	≥ 3 yo: 1 drop in affected eye(s) twice daily	1 drop in the affected eye(s) twice daily	Same as above

Mast Cell Stabilizer Ophthalmic Drops

Product (active)	Generic?	Pediatric Dose	Adult Dose	Counseling Points
Alamast (pemirolast)	No	> 3 yo: 1 to 2 drops in affected eye(s) 4 times a day	1 to 2 drops in affected eye(s) 4 times a day	Remove contact lenses before use and do not reinsert if eyes are red
Alocril (nedocromil)	No	≥ 3 yo: 1 drop in each eye twice daily	1 drop in each eye twice daily	Same as above
Alomide (lodoxamide)**	No	≥ 2 yo: 1 to 2 drops in eye(s) 4 times a day	1 to 2 drops in eye(s) 4 times a day	Do not wear contact lenses during treatment
Crolom (cromolyn)**	Yes	> 4 yo: 1 to 2 drops in each eye 4 to 6 times a day	1 to 2 drops in each eye 4 to 6 times a day	Do not wear contact lenses during treatment

* Zaditor is now available without prescription
** Alomide and Crolom are FDA indicated for vernal conjunctivitis. All others are FDA indicated for allergic conjunctivitis

P.R.N.

P.R.N. (ISSN # 1941-9481)
is published monthly by:
PRN Publishing LLC
68-37 Yellowstone Boulevard
Suite C-22
Forest Hills, New York 11375
Phone & Fax (718) 263-4632

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ASK PRN...

There exist a number of prescription products which contain controlled substances, but are not scheduled as such by the DEA (Fioricet, Estratest). What is the regulatory basis of these exceptions, and are these products considered controlled substances under New York State law?

The products you mentioned, and several others, have been specifically exempted from controlled substance status under federal law. Section 1308.32 of Title 21 of the Code of Federal regulations (21 CFR) exempts certain prescription products which contain **butalbital**, **phenobarbital**, or **chlordiazepoxide**. Section 1308.34 of 21 CFR exempts certain anabolic steroids, specifically **methyltestosterone** when combined with esterified estrogens. These drugs are also exempted from controlled substance status in New York State by virtue of section 80.3 of the Rules and Regulations on Controlled Substances. A partial list of the exempted products includes the following:

21 CFR 1308.32

Donnatal and generics
Esgic and generics
Esgic Plus and generics
Fioricet and generics
Librax and generics
Phrenilin and generics

21 CFR 1308.34

Esterified Estrogens and Methyltestosterone
(former brand names include:
Essian and Essian HS
Estratest and Estratest HS
Premarin with Methyltestosterone
Syntest DS and Syntest HS)

GOT QUESTIONS? WE HAVE ANSWERS!
Send your questions to us at:
askprn@prnnewsletter.com

PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

DID YOU KNOW?

DID YOU KNOW that the original formula of the soft drink 7 Up contained lithium citrate, a mood stabilizer which is now, of course, a prescription-only drug? Invented by Charles Leiper Grigg in 1929, 7 Up was originally sold under the name *Bib-Label Lithiated lemon-Lime Soda*. In 1936, Grigg changed the company name to Seven Up. One of the few major soft drinks invented by a non-pharmacist, it became at one time the third best selling soda in the United States and reached iconic status through the highly successful "Un-Cola" advertising campaign of the 1970s. By the way, the lithium citrate was removed from 7 Up in 1950, just before lithium became a prescription drug!

PHARMACY FUN

This month's puzzle is all about alliteration; you know, the popular practice of placing a plethora of particularly pleasant and similar sounding syllables at the start of several sequential segments of a sentence. Now if that wasn't a good enough example try this: Peter Piper Picked a Peck of Pickled Peppers! For each alliterative sentence below, identify the brand-name drug that matches the description. The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. **A Purple Pill for Post-Prandial Pain**
2. **A Maroon Medicine for Menopausal Moods**
3. **A Blue Bolus for Better Bonding**
4. **A Pink Pill for Prolonged Patency of Percutaneous Procedures**

Answers to last month's **PHARMACY FUN**:
1. Lipitor 20 mg 2. Plavix 75 mg 3. Abilify 10 mg 4. Singulair 10 mg 5. Zyprexa 5 mg 6. Lexapro 20 mg 7. Tricor 145 mg 8. Lyrica 50 mg 9. Diovan 80 mg 10. Januvia 100 mg

References:
1. Jalyn [package insert]. Research Triangle Park, NC: GlaxoSmithKline; June, 2010.
2. Dulera [package insert]. Whitehouse Station, NJ: Merck & Coo., Inc.: 2010.