P.R.N.

ISSN # 1941-9481

www.prnnewsletter.com

No. 44 | **The Newsletter for Community Pharmacists** | **May/June, 2012**

What's Inside…

FDA NEWS

FDA Position on Long-Term Bisphosphonate Use

The FDA has weighed in on the question of how long bisphosphonates should be taken to reduce the risk of fracture in patients with osteoporosis. In a review published in *The New England Journal of Medicine*, the agency concludes that most patients do not receive any additional benefit from taking the drug for more than 3 to 5 years, although the author did not make any specific recommendations for discontinuation of the drug. The concern over long-term use of bisphosphonates stems from reports of serious adverse events, including femoral fractures, jaw necrosis, and esophageal cancer, in patients on the drugs for many years. In a companion article published in the *Journal*, several specific recommendations are made by endocrinologists, including the following:

- **Patients with acceptable bone mineral density after 3 to 5 years of treatment are unlikely to benefit from continued therapy.**
- **Patients with low bone mineral density after 3 to 5 years of treatment, or who have an existing vertebral fracture, may benefit from continued therapy.**

.....NEW DRUGS.....NEW DRUGS.....NEW DRUGS.....

BELVIQ (Lorcaserin HCl).
Category: Anorexiant.
Initial dose: 10 mg twice daily.
MDD: 10 mg twice daily.

The FDA has approved Belviq, the first new diet pill approved by the agency in 13 years. Belviq will be marketed by Eisai, Inc. once the DEA has scheduled the drug (the FDA has recommended that Belviq be classified as a controlled substance). Belviq is a serotonin 2C receptor agonist indicated for weight management in adults with an initial body mass index (BMI) of 30 kg/m^2 or greater (obese) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes). Belviq should be discontinued if a 5% weight loss has not been achieved by week 12 of treatment. Because of the risk of Serotonin Syndrome, extreme caution should be used in combining Belviq with other serotonergic drugs, such as SSRIs, SNRIs, MAOIs, triptans, bupropion, dextromethorphan, or St. John's Wort.

STENDRA (Avanafil).
Category: PDE-5 inhibitor for erectile dysfunction.
Initial dose: 100 mg approximately 30 minutes before sexual activity as needed.
MDD: 200 mg.

Vivus, Inc. has announced approval of Stendra, the fourth phosphodiesterase-5 inhibitor for erectile dysfunction to be marketed in the U.S. As with other PDE-5 inhibitors, Stendra is contraindicated in patients using any form of organic nitrate. Patients on stable alpha-blocker therapy should be started with the 50 mg dose.

DYMISTA (Azelastine HCl and Fluticasone Propionate Nasal Spray).
Category: Combination nasal steroid and nasal antihistamine.
Initial dose: 1 spray in each nostril twice a day.
MDD: 1 spray in each nostril twice a day.

Meda Pharmaceuticals has been granted approval to market Dymista, a combination nasal spray containing both an antihistamine and steroid. Dymista is indicated for the relief of symptoms of seasonal allergic rhinitis in patients 12 years of age and older. The most common adverse reactions seen in clinical trials were dysgeusia, epistaxis, and headache. Patients should be instructed to prime the pump before initial use and when it has not been used for 14 days.

MYRBETRIQ (Mirabegron).
Category: Beta-3 agonist for overactive bladder.
Initial dose: 25 mg once daily, with or without food.
MDD: 50 mg.

The FDA has approved Myrbetriq, the first and only beta-3 agonist approved for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. Myrbetriq is an extended-release tablet which should be swallowed whole with water and not chewed, divided, or crushed. Because Myrbetriq is a beta receptor agonist, it can increase blood pressure. Periodic blood pressure determinations are recommended, especially in hypertensive patients. Myrbetriq is not recommended for use in patients with severe uncontrolled hypertension, severe hepatic disease, or end stage renal disease.

Glaxo Fined $3 Billion in Largest Ever Pharma Fraud Case

The British pharmaceutical giant GlaxoSmithKline has pleaded guilty to criminal charges involving failure to report critical safety data and marketing drugs for unapproved uses, leading to a 1 billion dollar fine from the U.S. Department of Justice. The company will pay another $2 billion in fines to settle civil charges of marketing violations. The total price tag of $3 billion is the largest penalty to date levied against a drug company. The criminal charges involved **Paxil**, **Wellbutrin**, and **Avandia**. In the case of Paxil, the company illegally promoted the drug's use in children and teenagers, despite the fact that the company had data from its own trials showing an increase in suicides in teenagers taking the drug. Glaxo promoted Wellbutrin for everything from weight loss to sexual dysfunction without FDA approval, and, in perhaps the most serious case, the company withheld data demonstrating that Avandia increased the risk of heart attack, stroke, and death. While the actions of Glaxo leadership undoubtedly led to a number of avoidable patient deaths, no executives were charged or prosecuted in this case. And the 3 billion dollar fine, while the largest to date, pales in comparison to the combined $27.9 billion in sales the company realized from the three drugs.[1]

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Preferred Drug Program Update

The following changes to the New York State Medicaid Preferred Drug program are scheduled to take effect on **July 12, 2012**:

Preferred Agents:

Dulera
ProAir HFA

Non-Preferred Agents:

Celebrex
Crestor
Daliresp
Dextroamphetamine SR
Diflunisal
Effexor XR
Etodolac SA
Fenoprofen
Focalin
Ketoprofen SA
Meclofenamate
Mefanamic Acid
Nexium
Omeprazole OTC
Savella
Tolmetin
Valturna
Ventolin HFA

Dispense Brand When Less Expensive Program Update

Effective **May 25, 2012**, Zyprexa will be removed from the New York State Medicaid Dispense Brand When Less Expensive Program, which allows pharmacists to dispense certain brand name drugs even if the prescriber has not indicated "Dispense As Written." The current list of drugs included in the program follows:

Adderall XR	**Epivir**
Arixtra	**Kadian**
Astelin	**Lexapro**
Carbatrol	**Lovenox**
Combivir	**Nasacort AQ**
Concerta	**Uroxatral**
Diastat	**Valtrex**
Geodon	

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Changes and Additions to Controlled Substance Prescriptions

A common problem facing community pharmacists is the presentation of a prescription for a controlled substance which is missing legally required information. Additionally, there are often clinical, insurance coverage, or patient preference issues which require changes to be made to such prescriptions. Not surprisingly, one of the most frequent queries we receive at ***PRN*** involves the question of which changes or additions can legally be made to such prescriptions. The chart below, which applies to both C-II and C-III-IV-V prescriptions, is based on sections 80.69(l), 80.69(m), 80.73(m) and 80.73(n) of the Rules and Regulations on Controlled Substances in New York State, also known as "Part 80." The regulations also specify that a pharmacist must document the addition or change by indicating the date the oral authorization was received on the prescription and affixing his or her signature. In the case of changes to a prescription, the pharmacist must also indicate the change on the prescription and initial the change.

N.Y. STATE REGULATIONS ON ADDITIONS AND CHANGES TO CONTROLLED SUBSTANCE PRESCRIPTIONS

ADDITIONS TO CONTROLLED SUBSTANCE RX		CHANGES TO CONTROLLED SUBSTANCE RX	
Pharmacist may add *without* prescriber's authorization	**Pharmacist may add *with* prescriber's authorization**	**Pharmacist may change *without* prescriber's authorization**	**Pharmacist may change *with* prescriber's authorization**
• **Patient's address** • **Patient's sex** • **Patient's age**	• **Prescriber's DEA #** • **Institution's DEA #** • **Drug strength** • **Directions for use** • **Maximum daily dose** • **Condition code**	• **Patient's address** • **Patient's sex** • **Patient's age**	• **Prescriber's DEA #** • **Institution's DEA #** • **Drug strength** • **Quantity** • **Dosage form** • **Directions for use** • **Maximum daily dose** • **Condition code**
NEVER ADD		***NEVER CHANGE***	
Patient's name **Prescriber's signature** **Date written** **Drug name** **Quantity**		**Patient's name** **Prescriber's signature** **Date written** **Drug name**	

Feature Article..

REVIEW OF SUN AND HEAT-RELATED ILLNESS

Summer Is Upon Us, and with it comes a whole host of maladies peculiar to the time between the summer solstice and the autumnal equinox. Chief among these warm-weather complaints are sunburn and heat exhaustion, but there are a number of other conditions related to the sun that pharmacists may come across in their practice. Below is a review of the most common of these, along with the latest treatment recommendations.

Sunburn

The most common sun-related illness is sunburn, which can begin after as little as 15 minutes of sun exposure, depending on skin type and time of day. Symptoms generally appear in 1 to 24 hours, and peak at about 72 hours. Possible complications of intense or frequent sunburn include photoaging (dry, wrinkled skin, etc.), actinic keratoses, and skin cancer.

Symptoms:

- **Redness of exposed skin**
- **Skin warm to the touch**
- **Skin painful or tender**
- **Swelling**
- **Development of fluid-filled blister**
- **Constitutional symptoms (headache, fever, chills, weakness) may develop if a large area is affected**

Treatment:

- **Avoid further sun exposure**
- **Drink plenty of fluids**
- **Apply cool water compresses to skin or take a cool bath**
- **Take an NSAID (e.g., ibuprofen) to reduce pain and swelling**
- **Apply a moisturizer, preferably one containing aloe vera. Topical hydrocortisone may also be helpful for itching and inflammation**
- **Avoid topical products with anesthetics, such as benzocaine, which may cause contact dermatitis**
- **If blisters form, do not attempt to break them. When blisters rupture, apply antibiotic cream or ointment**

Heat Cramps

Heat cramps are painful muscle spasms resulting from loss of fluids and electrolytes during exertion in hot weather. Treatment consists of rest, replenishment of fluids and electrolytes, and passive stretching and massage of the affected muscle group.

Heat Exhaustion

Heat exhaustion is a syndrome resulting from a decreased capacity to regulate body temperature due to dehydration and exposure to heat. Symptoms included **profuse sweating, rapid heart rate, cool, moist skin, headache, fatigue, dizziness, and nausea**. Temperature may be mildly elevated, not exceeding 103° F. Treatment consists of fluid replacement, resting in a cool place (preferably air conditioned), and applying cool water to the skin. If not recognized and properly treated, heat exhaustion can progress to a much more serious condition known as heatstroke.

Heatstroke

Heatstroke is a serious medical condition requiring emergency medical treatment. Heatstroke occurs when the body loses the ability to regulate internal temperature, and may result from untreated heat exhaustion. Symptoms include **temperature of 104°F or greater, dry, hot skin, a lack of sweating, rapid heart rate and rapid breathing, nausea, vomiting, and altered mental status**. Treatment consists of IV hydration and various cooling techniques to lower body temperature. Ice water immersion can be used, but evaporative cooling methods are preferred, such as spraying a continual cool mist on the patient while fanning and massaging the skin. Benzodiazepines such as diazepam or lorazepam may be used to reduce shivering and prevent seizures.

Sun Allergy

The term "sun allergy" represents a range of conditions in which patients exhibit photosensitivity reactions. The major types of sun allergy are:

1. **Polymorphic Light Eruption (PMLE):** Symptoms appear within 30 minutes to several hours after sun exposure and include itchy, red skin with small bumps or plaques. PMLE is the most common sun allergy and is most often seen in girls and women under age 30. Treatment includes oral antihistamines, topical corticosteroids, and moderation of sun exposure. More severe cases may require a short course of oral steroids. Some patients respond to hydroxychloroquine 200 mg bid to tid.
2. **Solar Urticaria:** Symptoms include hives, itching, and blistering and can develop within minutes of sun exposure, even in areas of skin covered by clothing. If large areas are affected, patients may experience syncope, dizziness, and wheezing. Treatment includes oral antihistamines and desensitization with psoralen plus UVA (PUVA).
3. **Actinic Prurigo:** A chronic condition characterized by nodular lesions which may persist throughout the year, worsening in the summer months. There is a hereditary component, with American Indian populations most commonly affected. Symptoms first appear within hours or days of sun exposure. Approximately 75% of patients present with cheilitis (inflammation and cracking of the lips), and 45% experience conjunctivitis. Treatment includes topical steroids and sun avoidance. Resistant cases have been treated with some success using various systemic drug therapies, including thalidomide, hydroxychloroquine, and pentoxyphylline.

P.R.N.

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

Founder and Editor:
James Murphy, RPh

Medical Liaison:
Deborah Blenner, MD

Marketing:
Michelle Ye

The information contained in P.R.N. is for educational purposes only. Always use professional judgment in clinical practice.

We welcome your input. Please forward any comments, suggestions, or questions to us at:
askprn@prnnewsletter.com

Visit us on the web at:
www.prnnewsletter.com

SUBSCRIPTION INFORMATION

Subscriptions are available:
One year (6 issues)……..…$45.00
(Student Discount Available Online)

To pay by credit card via secure server go to the **SERVICES** page of our website: **www.prnnewsletter.com**
or
Send a check or money order payable to PRN Publishing to:

PRN Publishing
68-37 Yellowstone Boulevard
Suite C-22
Forest Hills, New York 11375

ASK PRN...

What are the rules for partially filling prescriptions for controlled substances in New York State?

In the case of Schedule II drugs, a prescription may be partially filled, at the patient's request, after the pharmacist has received oral authorization to change the quantity from the prescriber. The remaining quantity is voided and may not be dispensed. On the other hand, if a partial *quantity* is dispensed by a pharmacist due to an out of stock situation, the remaining quantity may be dispensed within 72 hours. After 72 hours the remaining quantity is voided. For Schedule III-IV-V drugs, partial filling at the patient's request is allowed under section 80.74 of the Rules and Regulations on Controlled Substances in New York State, which states the following:

1. **Each partial filling is recorded in the same manner as a refill.**
2. **The total quantity dispensed does not exceed the total quantity prescribed for a 30 day period.**

Note that "recorded in the same manner as a refill" refers to documenting the partial fill on the original Rx, but does not *add* refills to the prescription. Any quantity remaining from a partial fill or partial refill must be dispensed within the 30 day life of that fill or refill; after 30 days any remaining quantity is voided.

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 laboratory in New Jersey where Librium and Valium were invented is being shut down? The site, in Nutley, N.J., served as the American headquarters for the Swiss pharmaceutical giant Roche for 80 years, but will be closed by the end of 2013. In 1960, the Polish pharmacist and chemist Leo Sternbach developed the first benzodiazepine, chlordiazepoxide (Librium), at the Nutley facility. Three years later Sternbach followed up this discovery with an even more important breakthrough: he produced diazepam (Valium), which became the best selling pharmaceutical in the United States between 1969 and 1982.

PHARMACY FUN

It's rebus time again, G.I. edition! Can you decipher the names of the gastrointestinal drugs in the picture puzzles below? The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. Z +  + N

2.  +  + A

3.  +  + 

Answers to last month's **PHARMACY FUN**:
1. Yaz 2. Heather 3. Errin 4. Yasmin 5. Amethyst 6. Portia

References:
1. Katie Thomas, Michael S. Schmidt, "Glaxo Agrees to Pay $3 Billion in Fraud Settlement," *New York Times*, July 2, 2012.