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FDA NEWS

FDA Warns of Dosing Errors Involving Noxafil

The FDA has issued a Drug Safety Communication regarding medication errors resulting from the difference in dosing regimens between the two available oral formulations of the antifungal **Noxafil** (posaconazole). According to the announcement, one case resulted in death and another in hospitalization. Noxafil extended-release tablets are available in 100 mg tablets and are indicated for the prophylaxis of invasive *aspergillus* and *candida* infections. Noxafil oral suspension is available as 200 mg per teaspoonful (40 mg/mL) liquid. The extended-release tablets require a loading dose for this indication, the suspension does not. The recommended dosage for each is listed in the table below:

Noxafil Delayed-Release Tablets
Loading dose: 300 mg (three 100 mg tablets) twice a day on the first day
Maintenance dose: 300 mg (three 100 mg tablets) once a day, starting on the second day

Noxafil Oral Suspension
200 mg (5 mL) three times a day

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

ADZENYS XR-ODT (Amphetamine extended-release orally disintegrating tablet)
Category: CNS stimulant for ADHD
Initial Dose: 6.3 mg once daily in AM
MDD: *Patients 6 to 12 years*: 18.8 mg once daily; *patients 13 to 17 years*: 12.5 mg once daily

Neos Therapeutics, Inc. will introduce Adzenys XR-ODT, an extended-release orally disintegrating form of amphetamine for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older. Adzenys was approved by the FDA through the 505(b)(2) pathway based on studies that established bioequivalence to **Adderall XR**. As a result, it is possible to determine the equivalent dose when switching patients to the new dosage form, using the following chart:

ADZENYS XR-ODT	**3.1 mg**	**6.3 mg**	**9.4 mg**
ADDERALL XR	**5 mg**	**10 mg**	**15 mg**

ADZENYS XR-ODT	**12.5 mg**	**15.7 mg**	**18.8 mg**
ADDERALL XR	**20 mg**	**25 mg**	**30 mg**

If switching patients from any other amphetamine products, discontinue that treatment, and titrate with Adzenys XR-ODT. Do not substitute for other amphetamine products on a milligram-per-milligram basis because of different amphetamine base compositions and pharmacokinetic profiles.

EMVERM (Mebendazole chewable tablets)
Category: Anthelmintic
Initial Dose: 100 mg twice daily
MDD: 200 mg

Impax Laboratories, Inc. will reintroduce the anthelmintic mebendazole under the brand name Emverm. The drug was originally introduced as **Vermox** in 1974, and the last available generic version was discontinued by Teva in October, 2011. Pricing information is unavailable as yet, so it is not yet known if this will be yet another case of a once inexpensive generic drug being repackaged and sold at a much higher price. Emverm is indicated for the treatment pinworm, whipworm, common roundworm, and common and American hookworm in either single or mixed infections, according to the following dosing schedule:

Pinworm (enterobiasis)	One tablet, once
Whipworm (trichuriasis)	One tablet morning and evening for 3 consecutive days
Common Roundworm (ascariasis)	One tablet morning and evening for 3 consecutive days
Hookworm	One tablet morning and evening for 3 consecutive days

If the patient is not cured three weeks after treatment, a second course of treatment is advised. To prevent reinfection, experts recommend washing hands and fingernails with soap often during the day, especially before eating and after using the bathroom, and washing all fruits and vegetables or cooking them thoroughly.

Widespread Use of PPIs Questioned Again by Two New Studies

Two recent studies have cast doubt on the safety of one of the most popular classes of drugs in the United States. Proton Pump Inhibitors (PPIs), which include **Aciphex**, **Prevacid**, **Prilosec**, **Protonix**, and **Nexium**, are used by 15 to 20 million Americans in any given year, with annual sales topping 13 billion dollars. Over the years, research has shown an association between long-term PPI use and increased risk for bone fractures, pneumonia, *C. difficile* infection, and vitamin and mineral deficiencies. This month, two new studies appeared in the Journal of the American Medical Association (JAMA); one showed an association between PPI use and chronic kidney disease, the other suggested a possible increased risk of dementia. While an association does not prove causality, it is probably fair to say that too many patients are taking PPIs for extended periods of time. Most retail pharmacists will tell you that they have a large number of patients taking these drugs indefinitely. And while certain conditions, such as *Barrett's esophagus* and *Zollinger-Ellison syndrome* may require constant PPI use, simple heartburn may be more safely treated with H2 inhibitors and dietary changes.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Updates to the Dispense Brand Name Drug when Less Expensive than Generic Program

Since our last issue, there have been two updates to the Dispense Brand Name Drug when Less Expensive than Generic Program, including 1 addition and 6 deletions:

Addition (effective 2/18/16)

Gleevec

Deletions (effective 1/21/16)

Depakote Sprinkle

Lidoderm

Trileptal Suspension

Deletions (effective 2/18/16)

Bactroban Cream

Kadian

Metrogel

Prescriptions for drugs in the program **do not require** *"DAW"* or *"Brand Medically Necessary"* on the prescription. The current list of drugs in the program is as follows:

Abilify	**Adderall XR**
Aggrenox	**Aldara**
Alphagan P 0.15	**Astepro**
Baraclude	**Catapres-TTS**
Cellcept Susp	**Combivir**
Copaxone	**Diastat**
Epivir HBV	**Exelon Patch**
Focalin XR	**Gabitril 2,4**
Gleevec	**Hepsera**
Mepron	**Myfortic**
Niaspan	**Patanase**
Protopic	**Pulmicort Respules**
Soriatane	**Tegretol Susp**
Tegretol XR	**Tobradex Susp**
TOBI	**Tricor**
Trilipix	**Trizivir**
Valcyte	**Wellbutrin**
Xeloda	**Xenazine**

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

The New York State Medical Marijuana Program

On January 7, 2016, New York State's medical marijuana program officially began operation. The program, created through the enactment of the Compassionate Care Act, makes New York the 23rd state to offer some form of legal access to marijuana. In order to be eligible for access to medical marijuana, patients must first be certified by a physician registered with the state. The criteria which must be met for certification are as follows: patients must have been diagnosed with a specific severe, debilitating, or life threatening condition *AND* suffer from one of a specific list of associated or complicating conditions. The diagnoses and conditions specified by the law are listed below:

Medical Diagnoses Required by Law for Certification	Associated Conditions Required by Law for Certification
• AIDS or HIV positive status	• Cachexia or wasting syndrome
• Amyotrophic lateral sclerosis (ALS)	• Seizures
• Cancer	• Severe nausea
• Epilepsy	• Severe or chronic pain resulting in substantial limitation of function
• Huntington's disease	• Severe or persistent muscle spasm
• Inflammatory bowel disease	
• Multiple sclerosis	
• Neuropathies	
• Spinal cord injury with intractable spasticity	

Registered Manufacturing and Dispensing Facilities

The law allows for the initial registration of 5 organizations to manufacture and dispense medical marijuana. After considering 43 applicants, the state selected the following companies, each of which is allowed up to 4 dispensing facilities:

ORGANIZATION NAME AND WEBSITE	DISPENSING FACILITY LOCATIONS
Bloomfield Industries, Inc. *www.bloomfieldindustries.com*	**Syracuse, NY** **Williamsville, NY**
Columbia Care NY, LLC *www.col-careny.com*	**New York, NY**
Etain, LLC *www.etainhealth.com*	**Albany, NY** **Kingston, NY**
PharmaCann, LLC *www.pharmacannis.com*	**Amherst, NY** **Liverpool, NY**
Vireo Health of New York, LLC *www.vireohealthny.com*	**White Plains, NY**

Pharmacist Participation

Section 1004.12(a) of the new regulations state that dispensing facilities shall not be open or in operation unless a licensed pharmacist is on the premises and directly supervising the activity within the facility. Pharmacists interested in working in a medial marijuana dispensing facility must complete a four-hour online course approved by the New York State Department of Health. The currently approved course is administered by a medial education website called **TheAnswerPage**, and can be accessed at ***www.theanswerpage.com***. The course is priced at $249.00 and will provide 4.5 hours of CE credit. Upon successful completion of the course, pharmacists may apply to the state for registration in the program.

Feature Article..

What's In A Name?: OC Comparison Chart

Shakespeare said it first, through Juliet: "What's in a name? That which we call a rose by any other name would smell as sweet." Case in point: oral contraceptives — each formula has so many unique names that it can be hard to remember which is equivalent to which. Making matters worse is the fact that there are some cases where two versions of the exact same formula are *not* equivalent to each other, according to the FDA Orange Book (e.g., Ortho Micronor and Nor-QD, and their respective generics). To aid in navigating this nomenclature conundrum, we offer the following equivalency chart.

Brand Name	AB-Rated Generics
Alesse (DSC)	Aubra, Aviane, Delyla, Falmina, Lutera, Orsythia
Cyclessa	Cesia*, Caziant, Velivet
Demulen (DSC)	Kelnor, Zovia
Estrostep Fe	Tilia Fe, Tri-Legest Fe
Femcon Fe	Wymza Fe*, Zenchent Fe, Zeosa
Generess Fe	Kaitlib Fe
Levlite (DSC)	Lessina, Sronyx
Loestrin	Blisovi, Gildess, Junel, Larin, Microgestin
Loestrin 24 Fe (DSC)	Blisovi 24 Fe, Gildess 24 Fe, Larin 24 Fe, Lomedia 24 Fe
Lo/Ovral	Cryselle, Elinest, Low-Ogestrel
LoSeasonique	Amethia Lo, Camrese Lo
Lybrel (DSC)	Amethyst
Micronor	Errin, Jencycla, Jolivette, Lyza, Sharobel
Mircette (DSC)	Azurette, Bekyree, Kariva, Kimidess, Pimtrea, Viorele
Modicon	Brevicon, Cyclafem 0.5/35, Necon 0.5/35, Nortrel 0.5/35, Wera
Nordette	Altavera, Chateal, Kurvelo, Levora, Marlissa, Portia

Brand Name	AB-Rated Generics
Nor-QD	Camila, Deblitane, Heather, Nora-BE*, Norlyroc
Ortho-Cept	Apri, Desogen, Emoquette, Enskyce, Reclipsen
Ortho Cyclen	Estarylla, Mono-Linyah, Mononessa*, Previfem, Sprintec
Ortho-Novum 1/35	Alyacen1/35, Cyclafem 1/35, Dasetta 1/35, Necon 1/35, Norinyl 1 + 35, Nortrel 1/35, Pirmella 1/35
Ortho-Novum 7/7/7	Alyacen 7/7/7, Cyclfem 7/7/7, Dasetta 7/7/7, Necon 7/7/7, Nortrel 7/7/7, Pirmella 7/7/7
Ortho Tri-Cyclen	Tri-Estarylla, Tri-Linyah, Trinessa*, Tri-Previfem, Tri-Sprintec
Ortho Tri-Cyclen Lo	Tri-Lo-Estarylla, Tri-Lo-Marzia, Tri-Lo-Sprintec
Ovcon 35	Balziva, Briellyn, Gildagia, Philith, Vyfemla, Zenchent
Seasonale	Introvale, Jolessa*, Quasense, Setlakin
Seasonique	Amethia, Ashlyna, Camrese*, Daysee
Tri-Norinyl	Aranelle, Leena*
Triphasil	Enpresse, Levonest, Myzilra, Trivora
Yasmin	Ocella*, Syeda, Zarah
Yaz	Gianvi*, Loryna, Nikki, Vestura

***Key*: DSC = Product discontinued**

*** = Authorized Generic** (an authorized generic is a lower priced version produced by the brand name manufacturer and marketed by a subsidiary or other licensed distributor. Since they are identical to the brand name product, authorized generics do not appear in the Orange Book).

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Founder and Editor:
James Murphy, RPh

Medical Liaison:
Deborah Blenner, MD

Marketing:
Michelle Ye

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askprn@prnnewsletter.com

Visit us on the web at:
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PRN Publishing
7636 113th Street
Suite 6C
Forest Hills, New York 11375

ASK PRN...

Are refill transfers permissible for prescriptions filled through the New York State Medicaid program?

Yes. As of March 26, 2015, the New York State Medicaid program allows for the transfer of a refill of a non-controlled substance prescription from one pharmacy to another, in accordance with the rules for refill transfers of the New York State Education Department (NYSED). In addition to the NYSED requirements, a serial number is also needed when billing Medicaid; for refill transfers a serial number of TTTTTTTT should be submitted. The origin code for refill transfers is 5. Keep in mind that New York State Medicaid policy states that a prescription may be refilled no more than 180 days after it has been initiated by the prescriber.

Can a refill of a prescription for hypodermic syringes and needles be transferred from one pharmacy to another?

Yes. Changes to the rules and regulations governing prescriptions for hypodermic syringes and needles now permit the transfer of a refill for such prescriptions from one pharmacy to another, according to the transfer regulations of the NYSED. In addition, several other regulations pertaining to hypodermic syringes and needles have been updated, including:

- Quantity and refill restrictions have been lifted for both written and oral prescriptions
- Oral prescriptions for hypodermic syringes and needles do not require a follow-up hard copy prescription
- Electronic prescriptions for hypodermic syringes and needles are permitted, and will become mandatory on March 27, 2016

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?

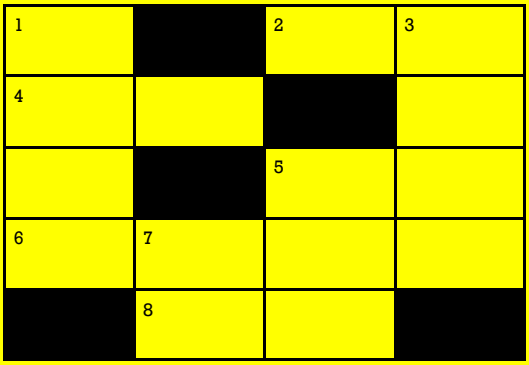
DID YOU KNOW that lithium carbonate, long before it was approved to treat bipolar disorder, was sold as an over-the-counter salt substitute? *Westsal* was a solution of lithium carbonate and citric acid promoted for cardiac patients on salt-restricted diets. It was banned after a 1949 JAMA article reporting on lithium toxicity as a complication of use of the product[1]. It wasn't until 1970 that lithium carbonate was approved by the FDA for mania. Interestingly, for many years lithium was also widely available as one of the ingredients in the popular soft drink *7 UP* (originally known as *Bib-Label Lithiated Lemon-Lime Soda*), which contained lithium citrate from its introduction in 1929 until it was removed from the product in 1950.

PHARMACY FUN

For the second month in a row, we are going with a crossword puzzle for *Pharmacy Fun*. And, just like last time, some of the answers come right from the content of this month's issue. Enjoy!

Across
2. Glyceryl guaiacolate
4. Before meals
5. Timed release
6. Indication for Adzenys XR
8. Subject of chart on page 3

Down
1. Effects enhanced by BZDs
3. PPI indication
5. Active ingredient of medical marijuana
7. Osteopathic physician



Answers to last month's ***PHARMACY FUN***:
Across: 1. TED 3. AD 4. CA 5. EPCS ***Down***: 1. TDAP 2. DOCS 3. ACE

References:
1. Corcoran, AC et al. Lithium poisoning from the use of salt substitutes. *JAMA*. 1949;139(11):685-688.