P.R.N.

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What's Inside…

FDA NEWS

Death Linked to Inappropriate Use of Ketoconazole Tablets

The FDA is reminding health care professionals to avoid the use of **ketoconazole** oral tablets to treat skin and nail fungal infections, which are *not* approved indications. As reported in July, 2013, ketoconazole can cause serious liver damage, adrenal gland problems, and harmful interactions with other medications that outweigh its benefit in treating these conditions. However, a recent office-based physician survey found that skin and nail fungal infections were the only diagnoses cited for the use of oral ketoconazole. Since the 2013 report, one patient death has been reported to the FDA, which was due to liver failure associated with oral ketoconazole prescribed to treat a fungal infection of the nails. Accordingly, ketoconazole tablets should only be used to treat serious fungal infections when other effective therapies are not available or are not tolerated by the patient.

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

BYVALSON (Nebivolol and Valsartan)
Category: Antihypertensive
Initial Dose: One 5 mg/80 mg tablet taken once daily
MDD: One tablet

Allergan has introduced the first-ever fixed-dose combination of a beta blocker (nebivolol) and a angiotensin II receptor blocker (valsartan). Byvalson is indicated for the treatment of hypertension. The recommended dose is one tablet daily, and maximum antihypertensive effects are attained within 2 to 4 weeks. Increasing the dose has not been shown to result in any meaningful further blood pressure reduction. As with all drugs which affect the renin-angiotensin system, Byvalson comes with a **black box warning** about possible injury to, or death of, a developing fetus exposed to the drug.

NUPLAZID (Pimavanserin)
Category: Atypical antipsychotic
Initial Dose: 34 mg (taken as two 17 mg tablets once daily, with or without food)
MDD: 34 mg

Acadia Pharmaceuticals has been granted FDA approval to market Nuplazid, an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. The recommended daily dose is two 17 mg tablets taken once daily. When taken with strong CYP3A4 inhibitors (e.g., ketoconazole) Nuplazid dose should be decreased by half. Due to QT interval prolongation, Nuplazid should not be used with other drugs that can increase the QT interval.

NARCAN NASAL SPRAY (Naloxone HCl)
Category: Opioid antagonist for the treatment of opioid overdose
Initial Dose: 4 mg as a single nasal spray
MDD: Additional doses may be given every 2 to 3 minutes until emergency medial assistance arrives

The FDA has approved a new nasal spray formulation of the opioid antagonist naloxone. Narcan nasal spray was developed specifically for the emergency treatment of known or suspected opioid overdose. Previously, only an injectable form of naloxone used with a nasal adapter was available for this route of treatment. Narcan nasal spray is available in packages of two intranasal sprays, each containing 4 mg of naloxone. If there is no response after the initial dose, additional doses may be given every 2 to 3 minutes in alternating nostrils until medical help arrives. Narcan nasal spray is not yet approved for the NYC standing order protocol for pharmacists (see page 3 for details), but can be used with written permission from the New York City Department of Health and Mental Hygiene.

GoNitro (Nitroglycerin sublingual powder)
Category: Antianginal
Initial Dose: 1 or 2 packets (400 to 800 mcg) under the tongue
MDD: 3 packets (1200 mcg) within a 15 minute period; if no relief seek emergency medical help

Espero Pharmaceuticals will market a new powder formulation of sublingual nitroglycerin for the acute relief of an attack of angina pectoris. GoNitro is also indicated for prophylaxis and may be used 5 to 10 minutes prior to engaging in any activities that might precipitate an acute attack of angina pectoris.

FDA Approves Name Brand Change for Brintellix

The FDA has approved a brand name change for the antidepressant **Brintellix** (vortioxetine), in order to avoid confusion with the blood-thinner **Brilinta** (ticagrelor). The new brand name will be **Trintellix**, and it is expected to be available in June (there will be a new NDC number for the renamed product). The FDA is taking this action in response to 55 reported cases involving confusion between the two drugs due to the similarity of their names. In one case, a patient was dispensed Brintellix in place of Brilinta, and after taking the wrong drug for 9 days was hospitalized after a fall, possible due to dizziness from taking Brintellix. In an even more serious case, a patient suffered bleeding and a partial collapse of a lung following a lung biopsy. The patient had been taking Brilinta, but the medical staff confused it with Brintellix in the patient's medial record and did not take the precautions necessary for a patient on a blood-thinner undergoing a procedure.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

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

There have recently been several updates to the Dispense Brand Name Drug when Less Expensive than Generic Program, including 1 addition and 3 deletions:

Addition (effective 5/26/2016)

Imitrex Kit (pens and cartridges)

Deletions (effective 5/26/2016)

Abilify tablets

Cymbalta

Renvela tablets

Prescriptions for drugs in the program **do not require** *"DAW"* or *"Brand Medically Necessary"* on the prescription, and have a generic copayment. If a drug is removed from the program, a new prescription is not required. The current list of drugs in the program is as follows:

Abilify Solution	**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**
Imitrex Kit	**Kapvay**
Mepron	**Myfortic**
Nasonex	**Niaspan**
Patanase	**Protopic**
Pulmicort Resp	**Soriatane**
Tegretol Susp	**Tegretol XR**
Tobradex Susp	**Tricor**
Trilipix	**Trizivir**
Valcyte	**Voltaren Gel**
Xeloda	**Xenazine**

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

New York State Enacts New Law Restricting Opioid Prescribing

On June 22, 2016, New York governor Andrew Cuomo signed into law a package of legislation designed to address the epidemic of opioid addiction currently plaguing the nation. The bill has 4 major components, labelled "A" through "D", which are discussed individually below. Pharmacists in New York State will be most affected by sections C and D, which deal with restricting initial opioid prescriptions to a 7-day supply or less, and obliging pharmacists to disseminate specific information to patients when dispensing controlled substances.

PART A: Pain Management Training

This section mandates that physicians and other opioid prescribers, including medical residents prescribing under an institutional DEA number, complete 3 hours of course work or training in pain management, palliative care, and addiction. The training must be approved by the Department of Health, must be completed by July 1, 2017, and must be taken again in every 3 year period thereafter.

PART B: Ends Prior Authorization for Treatment

Part B of the new law requires insurance companies to cover inpatient services for detoxification and rehabilitation *without* prior authorization or utilization review for the first 14 days of treatment, provided that the insurer is notified within 48 hours of admission.

PART C: Limits Initial Opioid Prescriptions to a 7-day Supply

Perhaps the most newsworthy section of the law, Part C limits initial prescriptions for opioids to a maximum of a 7-day supply. This act amends section 3331 of the Public Health Law to read:

> **"A practitioner...may not prescribe more than a seven-day supply of any schedule II, III, or IV opioid to an ultimate user upon the initial consultation or treatment of such user for acute pain. Upon any subsequent consultations for the same pain, the practitioner may issue...any appropriate renewal, refill, or new prescription for the opioid or any other drug.**
>
> **For the purpose of this subdivision, 'acute pain' shall mean pain, whether resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time. Such term shall not include chronic pain, pain being treated as part of cancer care, hospice, or other end-of-life care, or pain being treated as part of palliative care practices."**

This section of the law takes effect in 30 days (July 22, 2016).

PART D: Pharmacies to Provide Information when Dispensing Controlled Substance Prescriptions

This section tasks the Commissioner of Health with creating educational materials regarding the dangers of misuse and the potential for addiction to prescription controlled substances, treatment resources available, and the proper disposal of unused controlled substances. Such materials shall be made available to pharmacies and shall be distributed at the time of dispensing with any prescribed drug that is a controlled substance. At the option of the consumer, said materials may be distributed through electronic means. In addition, Part D states that registered pharmacies in New York State may offer counseling and referral services to customers purchasing hypodermic syringes for the purpose of: preventing injection drug abuse; the provisions of drug treatment; preventing and treating hepatitis C; preventing drug overdose; testing for the human immunodeficiency virus (HIV); and providing pre-exposure and non-occupational post-exposure prophylaxis. This section of the law takes effect in 120 days (October 20, 2016).

Feature Article..

NYC NALOXONE FOR OPIOID OVERDOSE PROGRAM

On December 17, 2015, New York City mayor Bill de Blasio announced that a standing order had been issued allowing naloxone to be dispensed without a prescription by pharmacies in the city. The order, signed by NYC Health Commissioner Mary T. Basset, M.D., is a non-patient specific prescription and pharmacist dispensing protocol. The specifics and requirements of the protocol are discussed below.

Requirements for Pharmacies

In order to dispense naloxone without a prescription, a pharmacy must have a signed non-patient specific protocol. This can be one obtained from an individual prescriber, or the New York City protocol issued by Health Commissioner Mary T. Bassett, M.D. The NYC protocol is available for download in PDF form on the home page of our website, ***www.prnnewsletter.com***, under the "What's New?" section.

Who Can Be Dispensed Naloxone?

People, 16 years of age and older, who voluntarily request naloxone, including:

- Any individual who is at risk of experiencing an opioid-related overdose
- Any family member, friend, or other person who may assist an individual at risk for an opioid-related overdose

What Must the Rx Label Contain?

- **Name of recipient/patient**
- **Prescriber name: Mary T. Bassett, MD**
- **Naloxone formulation and concentration**
- **Date dispensed**
- **Refills: 12 (recommended)**
- **The following terms:**
  - **"Dispensed per standing order**
  - **"Use as directed"**
  - **"Trained opioid overdose responder**

Responsibilities of Supervising Pharmacist

For pharmacies using the NYC protocol, it is the responsibility of the supervising pharmacist to sign the protocol and forward it by email to ***pharmacynaloxone@health.nyc.gov*** or by fax to **347-396-8889**. A signed copy of the protocol will be returned to the pharmacy for their records. In addition, the supervising pharmacist is responsible for ensuring that all registered pharmacists and pharmacy interns at their location have read and understood the protocol and have received appropriate education on overdose prevention and naloxone administration. Pharmacist education is available for CE credit through an on-line webinar, "*Reducing Opioid Overdose in New York City: Naloxone Non-Patient Specific Prescription and Dispensing for Pharmacists,"* by visiting ***www.nyc.gov/health*** and searching for "Pharmacy Naloxone."

Patient Education Protocol

When dispensing naloxone for opioid overdose, the pharmacist must provide a written patient handout ("Opioid Safety and How to Use Naloxone," available on our website at ***www.prnnewsletter.com***) and must review the information therein with person receiving the drug. The mandatory information to be covered includes:

1. **Naloxone overview** (opioid antagonist, works in 2-5 minutes, lasts 30-90 minutes, safe)
2. **Risk factors of opioid overdose** (using alone, mixing substances, changes in tolerance)
3. **Signs of opioid overdose** (Unconscious, slow or stopped breathing, blue fingernails/lips)
4. **Overdose response steps** (call 911, how to administer naloxone, stay with person)
5. **Additional information** (store at room temperature away from light, get refills, etc.)
6. **OASAS HOPEline referral information: OASAS HOPEline: call 1-877-846-7369 or visit *www.oasas.ny.gov/accesshelp***

Currently Approved Products for Use in the NYC Naloxone Protocol

	Intranasal	Intramuscular	Evzio Auto-Injector
Medication to be dispensed	**Naloxone 1mg/mL** solution in 2 x 2 mL pre-filled Luer-Lock syringes *NDC #76329-3369-01*	**Naloxone 0.4 mg/mL** solution in 2 x 1 mL single dose vials *NDC #00409-1215-01*	**Evzio 0.4 mg/mL** Auto-Injector in 1 x two-pack *NDC #60842-0030-01*
Required Devices	2 x Intranasal Mucosal Devices (MAD 300) available from Teleflex (866-246-6990)	2 x Intramuscular (IM) syringes: *3 mL, 25 G, 1 inch*	None
Patient Handout	*Opioid Safety and How to Use Naloxone* (or adapted materials)	*Opioid Safety and How to Use Naloxone* (or adapted materials)	*Opioid Safety and How to Use Naloxone* (or adapted materials)

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ASK PRN...

Is it true that practitioners who are "low volume" prescribers are exempt from New York State's mandatory electronic prescribing law?

Yes, but the exemption applies only to those prescribers who certify that they will issue no more than 25 prescriptions per year. Effective June 1, 2016, the Public Health Law (section 281) was amended to read:

"A practitioner shall not be required to issue prescriptions electronically if he or she certifies to the department, in a manner specified by the department, that he or she will not issue more than twenty-five prescriptions during a twelve month period. Prescriptions in both oral and written form for both controlled substances and non-controlled substances shall be included in determining whether the practitioner will reach the limit of twenty-five prescriptions."

Each independent practitioner must certify individually, but there is no review or approval process required. This certification may be renewed once yearly for a maximum of three twelve-month periods. If the prescriber needs to exceed the twenty-five prescription annual limit, the prescriber is then required to prescribe electronically or obtain a waiver from the requirement to electronically prescribe. Keep in mind that, as with all prescriber exemptions and waivers from electronic prescribing, **the pharmacist is NOT required to verify that a practitioner properly falls under one of the exceptions from the requirement to prescribe electronically.** Pharmacists may continue to dispense medications from valid written, oral, and fax prescriptions that are consistent with current laws and regulations.

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 disease we know as diabetes mellitus was first described by the Egyptian physician Hesy-Ra in 1552 B.C., in a document known as the Papyrus Ebers?[1] The disease gained the first part of its modern name from the Greek physician Aretaeus of Cappadocia in the first century A.D., who used the term *diabetes* (Greek for "siphon" or "passing through") to describe the condition of patients exhibiting polyuria. *Mellitus* (Greek for "honey" or "honey sweet") was added in 1675 by English physician Thomas Willis in recognition of the fact that the urine of diabetics was known to be sweet, which was later understood to be the result of glycosuria.

PHARMACY FUN

Many, if not most, drugs have more than one indication, and those indications are usually closely related, such as hypertension and heart disease. There are a number of drugs, however, which have been found useful for two or more seemingly unrelated conditions. For each of the following, can you name the one drug that has been used for both of the conditions listed? (Note: many of the secondary indications are off-label uses and may involve different dosage forms) The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. **Hypertension and Hirsutism**
2. **GERD and Warts**
3. **Schizophrenia and Hiccups**
4. **Arthritis and Patent Ductus Arteriosus**
5. **Unwanted Facial Hair and African Sleeping Sickness**
6. **Diabetes and Polycystic Ovary Syndrome**
7. **Angina and Stage Fright**
8. **Bacterial Infections and Syndrome of Inappropriate Antidiuretic Hormone (SIADH)**

Answers to last month's **PHARMACY FUN**:
1. Mentax 2. Betaxolol 3. Cefotaxime 4. Taxol 5. Metaxolone 6. Staxyn

References:
1. Canadian Diabetes Association's History of Diabetes. Accessed online at ***www.diabetes.ca*** on June 15, 2016.