P.R.N.

ISSN # 1941-9481

www.prnnewsletter.com

No. 63 | **The Newsletter for Community Pharmacists** | **July/August, 2018**

What's Inside…

FDA NEWS

FDA Will Reinforce Fluoroquinolone Safety Warnings

Once again, the FDA is sounding the alarm about the possibility of serious adverse effects associated with the use of oral and parenteral fluoroquinolone antibiotics. The agency will strengthen the current warnings in the prescribing information indicating that these antibiotics can cause significant decreases in blood sugar and certain mental health side effects. Blood sugar disturbances (high *and* low) are already included in drug labels, but new language will be added stating that drug-induced hypoglycemia can lead to coma. On the mental health side, warnings already exist on some individual drug labels, but the update will make the mental health side effects more prominent and consistent across the fluoroquinolone drug class. These side effects include disturbance in attention, disorientation, agitation, nervousness, memory impairment, and delirium.

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AIMOVIG (Erenumab-aooe).
Category: Migraine preventative.
Initial Dose: 70 mg once monthly.
MDD: 140 mg once monthly.

Amgen, Inc. has received FDA approval for Aimovig, a novel treatment for the prevention of migraine headaches in adults. Aimovig is a biologic drug classified as a calcitonin gene-related peptide (CGRP) receptor antagonist. CGRP is thought to be involved in migraine attacks by contributing to neurogenic inflammation and pain transmission. Given as a once-monthly subcutaneous injection, Aimovig has been shown in clinical trials to reduce migraine frequency by 1 to 2 headaches per month. The initial dose is one 70 mg injection monthly, which can be increased to 140 mg monthly, given as two consecutive 70 mg injections. The injection may be given in the abdomen, thigh, or upper arm as follows:

- **Leave the autoinjector at room temperature for 30 minutes before injecting.**
- **Pull the white cap straight off (do not leave off for more than 5 minutes).**
- **Stretch or pinch the injection site to create a firm surface. If injecting in the abdomen, avoid a 2 inch area around the navel. Upper arm injection is only for use if given to the patient by another person.**
- **Place the autoinjector on the skin at a 90 degree angle, push down on the skin, and then press the purple start button. A click will be audible.**
- **Keep pushing down on the skin. The injection could take about 15 seconds. When it is complete the injection window on the pen will turn yellow.**

ORILISSA (Elagolix).
Category: Gonadotropin-releasing hormone (GnRH) receptor antagonist.
Initial Dose: 150 mg once daily for up to 24 months
MDD: 200 mg twice daily for up to 6 months.

AbbVie, Inc. will introduce Orilissa, the first and only oral GnRH antagonist specifically designed for women with moderate to severe endometriosis pain. Orilissa is contraindicated in pregnancy, known osteoporosis, and severe hepatic impairment. The duration of treatment is limited because of dose- and duration-dependent decreases in bone mineral density (BMD): 150 mg daily for up to 24 months for endometriosis and 200 mg twice daily for up to 6 months for endometriosis with dyspareunia. Patients with moderate hepatic impairment should not exceed 150 mg daily for up to 6 months.

QBREXZA (Glycopyrronium cloth, 2.4%).
Category: Anticholinergic for axillary hyperhidrosis.
Initial Dose: Apply once daily.
MDD: Apply once daily.

Dermira, Inc. has been granted approval to market Qbrexza, a topical anticholinergic for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older. Primary axillary hyperhidrosis (excessive underarm sweating) is a chronic condition of unknown cause, which affects nearly 10 million people in the U.S. Qbrexza is a pre-moistened cloth which can be applied once every 24 hours. A single cloth should be used to apply Qbrexza to both underarms. Patients should wash their hands immediately after applying Qbrexza.

FDA Takes Action Against OTC Oral Pain and Teething Products

The FDA has issued a warning against the use of any over-the-counter (OTC) oral product containing benzocaine in children younger than 2 years of age. The alert is the result of the agency's review of 119 cases of benzocaine-associated methemoglobinemia reported between 2009 and 2017. Methemoglobinemia is a condition in which the amount of oxygen carried in the blood is greatly reduced, and which can be life-threatening. Most of the 119 cases studied were serious and required treatment; four patients, including one infant, died. In response to the FDA action, one manufacturer, Church and Dwight, Inc., has announced it will discontinue the entire line of **Orajel** teething products. The FDA will require a new warning on all OTC oral benzocaine products about the risk of methemoglobinemia, the symptoms of which include: pale, gray or blue-colored skin, lips, and nail beds, shortness of breath, fatigue, confusion, headache, lightheadedness, and fast heart rate. The symptoms may occur after using benzocaine for the first time, as well as after prior uses.

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 2 additions and 5 deletions:

Additions
Norvir tablets
Sustiva tablets

Deletions
Edecrin
Emend Tripack
Pataday
Reyataz
Valcyte solution

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:

Adderall XR
Aggrenox
Alphagan P 0.15%
Butrans
Catapres-TTS
Cellcept Susp
Copaxone 20 mL SQ
Diastat
Exelon patch
Focalin
Focalin XR
Fosrenol chewable tablets
Gleevec
Hepsera
Kapvay
Lexiva tablets
Norvir tablets
Protopic
Pulmicort respules 1 mg
Retin-A cream
Sustiva tablets
Tegretol Suspension
Tobradex suspension
Transderm-Scop
Trizivir
Vigamox
Voltaren gel
Xeloda
Xenazine
Zyflo CR

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

New York Pharmacists Prepare for Pediatric Vaccinations

On April 12, 2018, New York governor Andrew Cuomo signed into law a bill that, effective immediately, authorized licensed, certified pharmacists to administer influenza vaccine to children between 2 and 18 years of age, pursuant to a patient specific or non-patient specific order (e.g., a physician protocol). Since that legislation came at the end of last year's flu season, it is likely that most New York pharmacist have yet to vaccinate any children, making this year's upcoming season a challenging and unique one. In the next issue of PRN (#64), we will cover this year's approved vaccines and review techniques for administering vaccines to children.

Board of Regents Adopts Emergency Action

In response to the new immunization law, the Board of Regents adopted, as an emergency action, amendments to section 63.9 of the Regulations of the Commissioner of Education to implement the change. Additional emergency action was then taken to ensure that the new rule will remain continuously in effect until it can be permanently adopted at the Board's September meeting.

Review of Pharmacist Immunization in New York State

Below is a handy reference outlining pharmacist's immunization authority in New York State. In order to administer the following vaccines, a pharmacist must be licensed and registered, as well as certified for immunizations (the letter "I" in the pharmacist's license number indicates certification) and have current training in basic life support. All of the vaccines may be administered pursuant to a non-patient specific standing order or protocol. The protocol must conform with current ACIP recommendations; any vaccine given outside those recommendations would require a patient specific order (prescription); for example, Zostavax for a patient less than 60 years of age.

Vaccine	Products Available	Pharmacist's Restrictions	Notes, etc.
INFLUENZA	**Afluria, Flublok, Flucelvax, Fluzone**, etc. (see our next issue for full coverage of 2018/19 flu).	Patients 2 years of age and older.	Select appropriate product for patient (e.g., High Dose for patients 65 years of age and older).
PNEUMONIA	**Prevnar 13** **Pneumovax 23**	Patients 18 years of age and older. For patients under 65, a qualifying medical condition must exist.	Give Prevnar first, followed by Pneumovax at least 12 months later.
TDAP	**Boostrix** **Adacel**	Patients 18 years of age and older. Pregnant women, with *every* pregnancy, between 27 and 36 weeks gestation.	When possible, administer Boostrix to patients ≥65 y.o. (Adacel is approved for *up to* 64 y.o.)
MENINGITIS	**Menactra** **Menveo** **Bexsero** **Trumenba**	Patients 18 years of age and older, including first year college students and other high risk groups.	Menactra and Menveo cover meningococcal groups A, C, Y, and W-135. Bexsero and Trumenba cover group B.
SHINGLES	**Shingrix** **Zostavax**	Patients 50 years of age and older for Shingrix, 60 and older for Zostavax; otherwise a prescription is required.	Shingrix is now preferred over Zostavax. Shingrix requires 2 doses, given 2 to 6 months apart.

FEATURE ARTICLE...

Shingles: Etiology, Treatment, and Prevention

The CDC estimates that more than 1 million Americans develop shingles, or herpes zoster infection, every year, and that 1 out of every 3 people in the United States will suffer from the disease in their lifetime[1]. With the recent introduction of Shingrix, a highly effective vaccine against herpes zoster, pharmacists have a great opportunity to reduce the incidence of this painful and common syndrome. Below is a review of the disease, its treatment, and prevention.

The Virus

Shingles is a result of the reactivation of the virus that causes chicken pox (varicella). Varicella-zoster virus (VZV) is a DNA virus belonging to the family of herpes viruses (VZV is classified as human herpesvirus 3, or HHV-3). Other members of this virus family include herpes simplex 1 and 2, Epstein-Barr, cytomegalovirus, and roseola virus. The unique aspect of shingles is that it can only occur in people previously infected with chicken pox, or those given the chicken pox (varicella) vaccine. A person with an active shingles rash can not spread shingles to other people, but can transmit chicken pox to contacts who have never been exposed to the chicken pox virus or vaccine.

Signs and Symptoms

The earliest symptoms of shingles include pain, burning, or tingling of the skin. Some patients may experience fever, headache or malaise as well. Within 1 to 5 days, a red, painful rash appears in a single stripe on one side of the body or face, which evolves into fluid filled blisters. In immunocompromised patients, the rash can be widespread and may resemble chicken pox (disseminated zoster). The blisters dry up and crust over, usually within a week to 10 days, and the scabs clear up within a few weeks. If the shingles rash appears on the face near the eye, an ophthalmologic consult may be necessary to prevent ocular complications. Shingles in or near the ear may lead to Ramsay Hunt syndrome.

Treatment

The primary treatment of herpes zoster infection consists of antiviral therapy. The regimen of choice is valacyclovir 1000 mg three times a day for 7 days. Alternatives include famciclovir 500 mg three times a day for 7 days or acyclovir 800 mg five times a day for 7 days. NSAIDs or acetaminophen may be used to treat the pain. Wet compresses can soothe the rash and colloidal oatmeal baths may reduce itch. Pain which persists after shingles has cleared (postherpetic neuralgia) may be treated with anticonvulsants like gabapentin or pregabalin, antidepressants like nortriptyline, amitriptyline, or duloxetine, and with topical agents such as lidocaine patches or capsaicin.

Frequently Asked Questions

Q: Is shingles contagious?

A: No. Shingles can not be transmitted from one person to another; it is the reactivation of the patient's own dormant varicella virus. However, a person with an active shingles rash can transmit chicken pox if in close contact with an individual who has never been exposed to the varicella virus, either through having chicken pox or having received the varicella (chicken pox) vaccine.

Q: Can people who have never had chicken pox, but did receive the varicella (chicken pox) vaccine, develop shingles?

A: Yes. The varicella vaccine contains live attenuated varicella-zoster virus, which causes latent infection. The attenuated vaccine can reactivate and cause shingles; however, children vaccinated against varicella appear to have a lower risk of developing shingles than people who actually had chicken pox.

Q: Can a person who has previously been vaccinated with Zostavax receive the Shingrix vaccine?

A: Yes. Persons who have previously received Zostavax may be vaccinated with Shingrix as long as there has been at least an 8 week interval since the Zostavax vaccination.

Q: Can a person who has already had shingles receive the Shingrix vaccine?

Yes. Most people who develop shingles have only one episode during their lifetime, but it is possible to have a second or even a third episode. There is no specified amount of time needed to wait before administering Shingrix to patients who have had shingles, but vaccination should not occur during an acute episode of herpes zoster.

Prevention

The first vaccine to prevent shingles, **Zostavax** (zoster vaccine live) was licensed by the FDA in 2006. Zostavax is a live vaccine, which must be stored frozen, and which was found to be approximately 51% effective. In 2017, the second zoster vaccine, **Shingrix** (recombinant zoster vaccine) was approved. Shingrix is a non-live, lyophilized recombinant vaccine which has been shown to be 91% effective in preventing shingles. Shingrix is preferred over Zostavax by the CDC for the prevention of herpes zoster in adults aged 50 years and older. Here is a quick reference guide for pharmacists on the use of Shingrix:

- **Shingrix should be stored refrigerated at a temperature between 36°F and 46°F.**
- **Withdraw the entire contents of the adjuvant (blue-green cap) vial into a syringe. Slowly transfer to the antigen (brown cap) vial. Gently shake to mix contents. Withdraw 0.5 mL from the vial and inject immediately or refrigerate and use within 6 hours.**
- **Administer intramuscularly in the deltoid region of the upper arm. Two doses are required. The second dose may be administered between 2 and 6 months after the initial dose.**

P.R.N.

P.R.N. (ISSN # 1941-9481)
is published bi-monthly by:
PRN Publishing LLC
7636 113th Street
Suite 6C
Forest Hills, New York 11375
Phone & Fax (718) 263-4632

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ASK PRN...

When electronic prescribing became mandatory in New York State, a blanket waiver was issued to cover special circumstances in which e-prescribing was not possible. Is this waiver still in effect?

Yes. The waiver, issued by the Department of Health, was renewed in March of 2018 for another year. The specific situations in which electronic prescribing requirements may be waived, and a written or oral prescription may be issue instead, include the following:

- **Prescriptions (for a controlled or non-controlled substance) which contain 2 or more products to be compounded by a pharmacist.**
- **Prescriptions (for a controlled or non-controlled substance) which contain long or complicated directions.**
- **Non-patient specific prescriptions for opioid antagonists.**
- **Prescriptions (for a controlled or non-controlled substance) issued under a research protocol.**
- **Prescriptions (for a controlled or non-controlled substance) issued under approved protocols for expedited partner therapy, collaborative drug management or comprehensive medication management, or in response to a public health emergency that would allow a non-patient specific prescription.**
- **Prescriptions (for a controlled or non-controlled substance) which are required by the FDA to contain certain elements that are not able to be accomplished by electronic prescribing.**

The blanket waiver does not effect any general waivers issued to specific practitioners.

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, at one time, 1 out of every 5 drug stores in the United States was a Rexall? The franchise chain, started by Louis K. Liggett in 1903, had grown by the mid-1950s to nearly 12,000 stores (by comparison, McDonalds now has about 14,000). By 1977, however, it had all but ceased to exist. One of the more interesting chapters in its history concerned the "Rexall train," pictured below. In 1936, Liggett decided to hold a convention for his franchise druggists, but rather than ask them all to travel to one location for the event, he created a "convention on wheels," using the latest streamlined locomotive and passenger cars of the New York Central Railroad. The rolling convention stopped at 200 cities in 47 states and Canada during its tour.

PHARMACY FUN

Time for a little midsummer pharmacy word play. Turn up the AC, grab a cold drink, and set your mind to figuring out the drug names (could be brand-name or generic) suggested by the following literary doodles. The first reader to submit the correct answers to *puzzle@prnnewsletter.com* wins a set of *PRN* stylus pens.

1. **____Armstrong + ____Winfrey + "Better Call ____."**
2. **A shorter way to say "I was introduced to the construction site manager."**
3. **How you might greet Nicholas II of Russia.**
4. **It's also a musical form, and a Hyundai!**
5. **Dracula actor + "Last Dance" singer (first names).**
6. **Add a door to me, and I become an island in Manila bay.**

Answers to last month's ***PHARMACY FUN***:
Across: 1. Lantus 6. ESP 7. No 8. NPH 9. ID 10. TA 11. Eat 12. ss
Down: 1. Lente 2. Asp 3. NPH 4. Units 5. Sodas

References:
1. *About Shingles (Herpes Zoster)*. Retrieved from http://www.cdc.gov/shingles on August 4, 2018.