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What's Inside…

FDA NEWS

FDA Warns of Serious Sleepwalking Injuries with Sleep Medications

The Food and Drug Administration (FDA) has issued a Drug Safety Communication regarding rare but serious injuries associated with the use of prescription insomnia medications. The products in question include **Ambien** (zolpidem), **Lunesta** (eszopiclone), and **Sonata** (zaleplon). These agents have been implicated in case reports of complex sleep behaviors, which including sleepwalking, sleep driving, and engaging in other activities while not fully awake. The FDA identified 66 cases of complex sleep behaviors with these drugs, which resulted in serious injuries, including death. The agency is adding a new ***black-box warning*** to the drug's labels and medication guides, and also requiring a ***Contraindication*** to avoid use of these agents in patients who have previously experienced an episode of complex sleep behaviors with Ambien, Lunesta, or Sonata.

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

WAKIX (Pitolisant).
Category: Histamine-3 (H3) receptor antagonist/inverse agonist.
Initial Dose: 8.9 mg once daily in the morning upon wakening.
MDD: 35.6 mg once daily in the morning upon wakening.

The FDA has approved Harmony Biosciences' Wakix for the treatment of excessive daytime sleepiness in adult patients with narcolepsy. Wakix is the first histamine-3 receptor antagonist/inverse agonist available, and may exert its effect by increasing the production of histamine, a wake-promoting neurotransmitter in the brain. Wakix should be take once daily in the morning upon awakening, and should be titrated as follows: **Week 1:** 8.9 mg QD, **Week 2:** 17.8 mg QD, **Week 3:** May increase to the maximum dosage of 35.6 mg QD.

QTERNMET XR (Dapagliflozin, saxagliptin, and metformin)
Category: Anti-diabetic combination agent.
Initial Dose: 5 mg/ 5 mg/ 1000 mg once daily in the morning with food.
MDD: 10 mg/ 5 mg/ 2000 mg once daily in the morning with food.

AstraZeneca will market Qternmet XR, a new combination agent for the treatment of adults with type 2 diabetes mellitus. Qternmet XR is a long-acting combination of an SGLT2 inhibitor (dapagliflozin), a DDP-4 inhibitor (saxagliptin), and a biguanide (metformin). Qternmet XR is intended only for patients currently taking metformin. Due to the metformin component of Qternmet XR, the product contains a **black-box warning** regarding the risk of lactic acidosis, as well as instructions to discontinue before any iodinated contrast imaging procedure.

BAQSIMI (Glucagon nasal powder).
Category: Antihypoglycemic
Initial Dose: 3 mg single dose in one nostril.
MDD: If no response after 15 minutes, an additional 3 mg dose may be administered.

Eli Lily and Company has received FDA approval to market a new nasal powder formulation of glucagon. Glucagon, previously available only in injection form, is a single-chain polypeptide which increases blood glucose concentration by activating hepatic glucagon receptors, which stimulates glycogen breakdown and releases glucose from the liver. Baqsimi is indicated for the treatment of severe hypoglycemia in patients with diabetes ages 4 years and above. Administer by inserting the tip of the unit into one nostril and pressing the plunger all the way until the green line is no longer visible.

PRETOMANID (Pretomanid).
Category: Antitubercular agent.
Initial Dose: 200 mg once daily for 26 weeks (in conjunction with bedaquiline and linezolid). Swallow tablet whole with water.
MDD: 200 mg once daily for 26 weeks (in conjunction with bedaquiline and linezolid). Swallow tablet whole with water.

The non-profit organization TB Alliance has been granted approval for pretomanid, a new chemical entity used in the treatment of extensively drug-resistant tuberculosis (XDR-TB), which has been reported to have a 60% mortality rate with previous treatment regimens (see news report below). Pretomanid is part of a 26-week, three-drug treatment for XDR-TB, which also includes bedaquiline and linezolid. The combination regimen should be taken once daily with food.

Breakthrough Treatment Approved for Drug-Resistant Tuberculosis

The Food and Drug Administration has approved a new treatment regimen for extensively drug-resistant tuberculosis (XDR-TB) which, in a trial called Nix-TB, increased the cure rate from 34% to nearly 90%. The regimen, know as BPaL, consists of three drugs: bedaquiline, pretomanid, and linezolid, which are taken once daily for 26 weeks. Tuberculosis is now the world's deadliest infectious disease, having surpassed AIDS, and XDR-TB is its most deadly form. When XDR-TB first appeared in 2006, the mortality rate was close to 80 percent, and treatment consisted of a combination of up to 8 antibiotics, some by injection, daily for up to 2 years. The new treatment regimen includes the just-approved entity **pretomanid** (see *RX News* above), which was developed not by a pharmaceutical company, but by the non-profit organization TB Alliance, which is dedicated to finding faster-acting and affordable drug treatments to fight TB. The newly-approved regimen consists of pretomanid 200 mg once daily for 26 weeks, bedaquiline 400 mg once daily for 2 weeks, followed by 200 mg three times a week for 24 weeks, and linezolid 1200 mg daily for up to 26 weeks.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Pharmacy Deliver Policy

The New York State Medicaid program has a set of specific polices regarding the delivery of prescriptions by pharmacies to Medicaid members. These policies apply to prescription and over-the-counter drugs dispensed pursuant to a prescription or fiscal order submitted to Medicaid for reimbursement of any portion. These policies are summarized below:

- **All shipping and/or delivery costs are the responsibility of the provider. No delivery fee may be charged to the member.**
- **The pharmacy is responsible for delivery of the product to the intended recipient.**
- **Prior to processing the drug claim, the pharmacy must confirm that the drug is needed and that the drug has not been discontinued, changed, or is no longer necessary. The confirmation must be maintained in the member's patient record. AUTOMATIC REFILLS ARE NOT PERMITTED.**
- **Prior to delivery, the pharmacy must obtain consent from the member or the individual authorized to consent on the member's behalf to deliver; consent shall be maintained on the member's patient record.**
- **Only the member, or the authorized individual, may receive the delivery**
- **Pharmacy providers must obtain a signature from the member, or the authorized individual, to confirm the receipt of drugs.**
- **The pharmacy is responsible to replace lost, stolen, or misdirected drugs at no additional cost to the member or to the Medicaid program.**

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Pharmacy Interns Authorized to Administer Vaccines

On December 7, 2018, New York Governor Andrew Cuomo signed into law Assembly Bill A2857D, which authorizes pharmacy interns in New York State to administer immunizations. Although the law took effect immediately, the specifics of the certification process for interns had to be established by the Board of Pharmacy, which has recently published guidelines for interns to become immunizers. In terms of regulations, the law amends section 6806 of the Education Law, the new subdivisions of which are summarized below:

- ***2.*** **A pharmacy intern may receive a certificate of administration if he or she provides satisfactory evidence to the commissioner that he or she meets the requirements of subdivision 3 of this section.**
- ***3.*** **No pharmacy intern shall administer immunizing agents without receiving training satisfactory to the commissioner, which shall include, but not be limited to: techniques for screening individuals and obtaining informed consent; techniques of administration; indications, precautions, and contraindications in the use of agents, recordkeeping, and handling emergencies, including anaphylaxis and needlestick injuries. To receive a certification to administer immunizations, the pharmacy intern shall provide documentation, on a form prescribed by the department, from the dean or other appropriate official of the registered program that the intern has completed the required training, pursuant to regulations of the commissioner.**
- ***6.*** **In the case of a pharmacy intern, certified to administer immunizations, administration must be conducted under the immediate personal supervision of a licensed pharmacist certified to administer vaccines. A person receiving a vaccine must be informed that a pharmacy intern, certified to administer immunizations, will be administering the vaccine and of the option to receive the vaccination from a certified pharmacist.**

Pharmacy interns must apply to the New York State Board of Pharmacy (*www.op.nysed.gov/prof/pharm*) for certification to administer immunizations. Current intern permit holders must submit form ***PH20-I***, which is to be completed by the dean, or other appropriate official, of the pharmacy school in which he or she is enrolled. If the student has met all requirements, and the PH20-I is approved, his or her permit will be reissued with the "I" indicator after the permit number. As a reminder, here is a chart listing the vaccines which certified pharmacists and pharmacy interns may administer in New York State:

Vaccine	Products Available	Pharmacist's Restrictions
INFLUENZA	**Afluria, Flublok, Flucelvax, Fluzone**, etc. (see our next issue for full coverage of 2019/20 flu).	Patients 2 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.
TDAP	**Boostrix** **Adacel**	Patients 18 years of age and older. Pregnant women, with *every* pregnancy, between 27 and 36 weeks gestation.
MENINGITIS	**Menactra** **Bexsero** **Menveo** **Trumenba**	Patients 18 years of age and older, including first year college students and other high risk groups.
SHINGLES	**Shingrix** **Zostavax**	Patients 50 years of age and older for Shingrix, 60 and older for Zostavax; otherwise a prescription is required.

FEATURE ARTICLE...

MENINGITIS: A PRIMER FOR PHARMACISTS

Meningitis is an uncommon, but potentially deadly, disease, which can be caused by a variety of bacteria and viruses. Since 2013, pharmacists in New York have been authorized to administer vaccines for the prevention of meningitis caused by *Neisseria meningitidis*. The authorization was originally granted in response to a health crisis in New York City involving an deadly outbreak of meningitis among men who have sex with men (MSM). This expanded authority has also allowed for pharmacists to vaccinate a much larger population of patients who may need protection against meningococcal disease caused by *N. meningitidis*.

The Disease

Meningococcal disease is cause by *Neisseria meningitidis*, an aerobic, gram-negative diplococcus. Thirteen serogroups have been identified, five of which (A, B, C, W, and Y) cause almost all invasive disease. In the United States, most meningococcal disease is caused by types B, C, and Y[1]. Signs and symptoms include sudden onset fever, headache, and stiff neck. Even with appropriate treatment, the mortality rate is 10 to 15%, and, in overwhelming infections, death can occur within several hours of symptom onset. Meningococcal disease is spread from person-to-person through respiratory and throat secretions (coughing, kissing, sharing utensils). Up to 10% of the population are asymptomatic carriers of *N. meningitidis.*

Treatment and Prophylaxis

Meningitis is considered a neurologic emergency, necessitating immediate antibiotic treatment. Empiric therapy consists of **vancomycin** plus **cefotaxime** or **ceftriaxone**. If *N. meningitidis* is confirmed, the drug of choice is **penicillin G**; alternatives include **cefotaxime**, **ceftriaxone**, and **chloramphenicol**. Close contacts of the infected person are candidates for antimicrobial chemoprophylaxis. Close contacts include household members, child care center contacts, and people directly exposed to the patient's oral secretions. Approved regimens include: **rifampin** 600 mg twice a day for 2 days, **ciprofloxacin** 500 mg for one dose, and **ceftriaxone** 250 in a single intramuscular injection. Prophylaxis should begin within 24 hours of diagnosis.

Prevention

Primary prevention of meningococcal disease is accomplished by vaccination against *N. meningitidis*. There are currently four vaccines available in the United States (two others, *Menomune* and *MenHibrix*, have been discontinued). **Menactra** and **Menveo** protect against serogroups A, C, Y, and W-135. **Bexsero** and **Trumenba** protect against serogroup B. All four of these vaccines are for intramuscular injection in the deltoid muscle of the upper arm. With the exception of **Bexsero**, these vaccines are latex-free. FDA indications and Advisory Committee on Immunization Practices (ACIP) recommendations are listed in the tables below. Pharmacists in New York State are limited to vaccinating patients 18 years of age and older.

Group A, C, Y, and W-135 Vaccines

Vaccine	MENACTRA	MENVEO
Dosage Form	Solution in 0.5 mL single-dose vials.	Solution in 2 vials to be reconstituted to 0.5 mL.
FDA Age Indications	Ages 9 months to 55 years of age. *May also use in patients over 55.*	Ages 2 months to 55 years of age. *May also use in patients over 55.*
ACIP Adult Immunization Recommendations	• **Patients with a damaged or missing spleen or complement component deficiency.** • **People with HIV infection.** • **First-year college students living in residence halls.** • **People travelling to areas where meningitis is common and lab workers handling *N. meningitidis*.** • **Military recruits** • **People at risk due to a local outbreak.**	• **Patients with a damaged or missing spleen or complement component deficiency.** • **People with HIV infection.** • **First-year college students living in residence halls.** • **People travelling to areas where meningitis is common and lab workers handling *N. meningitidis*.** • **Military recruits** • **People at risk due to a local outbreak.**
Notes	For asplenic patients, do not co-administer with Prevnar.	After combining the 2 vials, shake well to reconstitute.

Group B Vaccines

Vaccine	BEXSERO	TRUMENBA
Dosage Form	Suspension in 0.5 mL prefilled syringe.	Suspension in 0.5 mL prefilled syringe.
FDA Age Indications	Ages 10 to 25 years of age. *May also use in patients over 25.*	Ages 10 to 25 years of age. *May also use in patients over 25.*
ACIP Adult Immunization Recommendations	• **Patients with a damaged or missing spleen.** • **Patients with complement component deficiency (an immune system disorder, which may also be caused by the drugs Soliris and Ultomiris).** • **Lab workers handling *N. meningitidis*.** • **People at risk due to a local outbreak.**	• **Patients with a damaged or missing spleen.** • **Patients with complement component deficiency (an immune system disorder, which may also be caused by the drugs Soliris and Ultomiris).** • **Lab workers handling *N. meningitidis*.** • **People at risk due to a local outbreak.**
Notes	Shake before administration. Tip cap contains **LATEX**.	Shake vigorously before administration.

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ASK PRN...

Our pharmacy uses Fluad to immunize patients 65 years and older against influenza. Some of these patients are candidates for Shingrix vaccination as well. Can the two vaccines be co-administered?

Co-administration of **Shingrix** and **Fluad** is NOT recommended at this time. Both Shingrix (Recombinant Zoster Vaccine) and Fluad (Inactivated Influenza Vaccine) contain adjuvants. Adjuvants are ingredients added to some vaccines to enhance the immune response. Commonly used adjuvants include aluminum, $AS01_b$ (Shingrix), and MF59 (Fluad). These additives work by stimulating the immune response and often cause more severe local and systemic reactions than non-adjuvanted vaccines. Since there are no studies demonstrating the safety and efficacy of co-administration of two adjuvanted vaccines, Shingrix and Fluad should not be given together. For patients 65 years and older who are candidates for both influenza and zoster vaccination, it is preferable to use a non-adjuvanted high dose influenza vaccine, such as **Fluzone High Dose**.

What is the difference between Fluad and Fluzone High Dose, the two influenza vaccines currently recommended for people age 65 and over? Is one preferred over the other?

Fluad is a standard-dose influenza vaccine to which an adjuvant called MF59 has been added to increase the immune response in older people, who produce fewer antibodies than younger adults. **Fluzone High Dose**, in contrast, has no adjuvant, but contains 4 times as much antigen as the standard dose. Both vaccines are designed to elicit a greater immune response in older adults, and since no head-to-head trials have yet been completed (several are underway), the Advisory Committee on Immunization Practices (ACIP) has not expressed a preference between the two vaccines.

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?

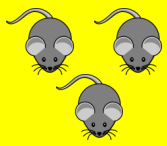
DID YOU KNOW that the word "vaccine" is derived from the Latin word *vaccinus*, which means "derived from a cow" ? The first successful vaccine, used to prevent smallpox, was developed in 1796 by English physician Edward Jenner. Jenner had noticed that milkmaids who had contracted cowpox (*variolae vaccinea*), a virus similar to, but much milder than smallpox, seemed to be immune to smallpox, a disease responsible for hundreds of millions of death through the centuries. He prepared an inoculation made from the scrapings of cowpox lesion and tested it on 24 subjects, all of whom developed immunity to smallpox. After centuries of devastation, it was announced on May 8, 1980 that smallpox had been eradicated, and the world was finally free of the disease.

PHARMACY FUN

It's rebus time again—celebrity edition! Be the first reader to correctly identify the following drug names and receive a set of PRN stylus pens! Submit your answers to *puzzle@prnnewsletter.com*.

1.  +  + **a**

2.  + 

3.    + **a** +  + **n**

4.  + 

Answers to last month's ***PHARMACY FUN***:
1. Mylanta 2. Maalox 3. Coricidin 4. Formula 44 5. Dramamine 6. Rhinocort

References:
1. Epidemiology and Prevention of Vaccine-Preventable Diseases (the "Pink Book"). Accessed online at *www.cdc.gov/vaccines/pubs/pinkbook*