P.R.N.

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What's Inside...

FDA NEWS

FDA Authorizes Evusheld for Pre-Exposure Prevention of COVID-19

The FDA has approved the first monoclonal antibody treatment for the pre-exposure prevention of COVID-19 in certain patients. The product is authorized only for individuals who are not currently infected and who have not recently been exposed to an infected individual. The authorization also requires that individuals have either:

- **Moderate to severely compromised immune systems due to a medical condition or due to taking immunosuppressive medications or treatments and may not mount an adequate response to COVID-19 vaccination.**
- **A history of severe adverse reactions to a COVID-19 vaccination and/or components of those vaccines, therefore vaccination with an available COVID-19 vaccine, according to the approved schedule, is not recommended.**

.....RX NEWS.....RX NEWS.....RX NEWS.....RX NEWS.....

VUITY (Pilocarpine HCl 1.25% ophth. sol).
Category: Cholinergic agonist for presbyopia.
Initial Dose: One drop in each eye once daily.
MDD: One drop in each eye once daily.

Allergan has announced FDA approval of Vuity (pilocarpine ophthalmic solution) for the treatment of presbyopia in adults. Presbyopia is an age-related loss of the eyes' ability to focus on nearby objects. Vuity works by contracting the iris sphincter muscle, constricting the pupil to improve near and intermediate visual acuity while maintaining some pupillary response to light. The recommended dosage is one drop in each eye once daily. Patients should be advised to exercise caution in night driving and other hazardous occupations in poor illumination.

TYRVAYA (Varenicline nasal solution).
Category: Cholinergic agonist for dry eye.
Initial Dose: One spray in each nostril twice daily (approximately 12 hours apart).
MDD: 4 sprays.

Oyster Point Pharma, Inc. has been granted FDA approval to market Tyrvaya (varenicline), a nasal spray indicated for the treatment of the signs and symptoms of dry eye disease. Varenicline, which is also the active ingredient in *Chantix*, is believed to work in dry eye disease by binding to nicotinic acetylcholine receptors and activating the trigeminal parasympathetic pathway, resulting in increased production of basal tear film. The recommended dosage is one spray in each nostril twice a day (approximately 12 hours apart). Prime with 7 actuations before initial use. Re-prime with 1 actuation if not used for more than 5 days.

First Oral Antiviral for the Treatment of COVID-19 Authorized

On December 22, 2021, the FDA issued the first-ever emergency use authorization for an oral antiviral for the treatment of COVID-19. Pfizer's **Paxlovid** contains nirmatrelvir, a SARS-CoV-2 protease inhibitor, and ritonavir, an HIV-1 protease inhibitor used to increase plasma levels of nirmatrelvir. Paxlovid is indicated for the treatment of mild-to-moderate COVID-19 disease in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who have tested positive for SARS-CoV-2 and who are at high risk for progression to severe COVID-19, including hospitalization or death. In clinical trials, Paxlovid reduced COVID-19 related hospitalizations or death by 88% compared to placebo. The FDA has indicated that Paxlovid is NOT authorized for initiation of treatment in patients requiring hospitalization due to severe or critical Covid-19, nor is it authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19. The recommended dosing[1] for Paxlovid is as follows:

- **Initiate Paxlovid treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.**
- **Administer orally with or without food.**
- **Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days.**

Photo courtesy of Pfizer

New York State Expands Pharmacists' Vaccination Authority

On November 2, 2021, New York State governor Kathy Hochul signed Senate bill 4807A into law, authorizing the permanent addition of several vaccines, including those for COVID-19, to the list of immunizations which pharmacists are permitted to administer to patients 18 years of age and older. In addition to codifying the authorization for vaccines to prevent COVID-19, the legislation added the following vaccines to the pharmacist's armamentarium: **Hepatitis A and B**, **Human Papillomavirus**, **Measles, Mumps, and Rubella**, and **Varicella**. Specifically , the bill amends section 6802 (subdivision 22) of the Education Law to indicate that pharmacists may administer: *"immunizations to prevent influenza, pneumococcal, acute herpes zoster, hepatitis A, hepatitis B, human papillomavirus, measles, mumps, rubella, COVID-19, meningococcal, tetanus, diphtheria, or pertussis disease."* The new law does not authorize unlicensed persons to administer immunizations, and will take effect on **January 31, 2022**. The chart below lists all vaccines that pharmacists in New York State will be authorized to administer as of January 31, 2022 (the COVID-19 vaccines are not included in this chart, and have been covered in previous issues of ***PRN***).

Vaccine	Products Available	Pharmacist's Restrictions	Notes
INFLUENZA	**Afluria, Fluad, Fluarix, Flublok, Flucelvax, Flulaval, Fluzone**	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 1 dose of Pneumovax for all patients 65 and older. *If PCV13 is indicated*, 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**	Patients 50 years of age and older.	Shingrix requires 2 doses, given 2 to 6 months apart.
HEPATITIS A & B	**Havrix (A)** **Engerix-B (B)** **Vaqta (A)** **Heplisav-B (B)** **Recombivax HB (B)** **Twinrix (A and B)**	Patients 18 years of age and older.	See page 3 for administration schedules.
HPV	**Gardasil 9**	Patients 18 to 45 years of age.	For patients receiving their first dose after age 15, a 3 dose regimen (0, 2, 6 months)
MEASLES, MUMPS, and RUBELLA	**M-M-R II**	Patients 18 years of age and older without evidence of immunity (persons born before 1957 are presumed to be immune).	Adults should receive 1 or 2 doses depending on risk factors (if giving 2 doses, space at least 4 weeks apart).
VARICELLA	**Varivax**	Patients 18 years of age and older without evidence of immunity (persons born before 1980 are presumed to be immune).	Varivax requires 2 doses, given at least 4 weeks apart.

FEATURE ARTICLE...

Review of Vaccines Added to Pharmacists' Authority

New York State has recently expanded the portfolio of vaccines pharmacists are authorized to administer to patients 18 years of age or older (see *Law Review* on page 2). Vaccines added to pharmacist's scope of practice in New York include hepatitis A and B, human papillomavirus, measles, mumps, and rubella, and varicella. Below is a brief review of each of these vaccines, including Advisory Committee on Immunization Practices (ACIP) recommendations for adults and dosing schedules.

Hepatitis A and B

There are two vaccines currently approved for prevention of Hepatitis A in adults, with slightly different dosing schedules:

Havrix: 2 dose series at 0 and 6-12 months (age 19+)

Vaqta: 2 dose series at 0 and 6-18 months (age 19+)

There are three vaccines currently approved for prevention of Hepatitis B in adults, with the following dosing schedules:

Engerix-B and **Recombivax HB:** 3 dose series at 0, 1, and 6 months

Heplisav-B: 2 dose series at 0 and 1 month

There is one combination Hepatitis A/Hepatitis B vaccine, doses as follows:

Twinrix: 3 dose series at 0, 1, and 6 months

Human Papillomavirus

Gardasil 9 is a 9-valent recombinant protein subunit HPV vaccine that protects against HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58, which are implicated in numerous cancers, including cervical, vulvar, anal, oropharyngeal and other head and neck cancers, as well as causing genital warts. Routine vaccination is recommended at 11 or 12, but may be given as early as age 9 or as late as age 14 in a 2 or 3 dose series. Persons receiving their first dose on or after their 15th birthday must receive a 3 dose series at 0, 2, and 6 months. If HPV vaccination schedule is interrupted, the series does not need to be restarted. Catch up vaccination is sufficient, and is recommended up to age 26. Shared clinical decision-making is advised regarding HPV vaccination for persons age 27 to 45 years of age. Gardasil 9 is not licensed or approved for use in persons older than 45 years of age.

Measles, Mumps and Rubella

MMR-II is an attenuated live vaccine containing measles, mumps, and rubella virus. The vaccine contains both gelatin and neomycin, and is administered subcutaneously. A 2 dose series is recommended for all children, with the first dose at 12 to 15 months of age and the second dose at age 4 to 6 years. Adult vaccination is recommended for persons without acceptable presumptive immunity (e.g., born before 1957, serologic evidence of immunity, laboratory confirmation of disease, or documentation of previous immunization). Dosing is as follows (minimum interval between doses is 4 weeks) :

- At least 1 dose of MMR for unvaccinated adults
- 2 doses MMR for students entering college or other post-high-school educational institutions
- 2 doses of MMR for healthcare personnel

Varicella

Varivax is a preparation of a strain of live, attenuated varicella virus. The vaccine contains both gelatin and neomycin, and is administered subcutaneously. A 2 dose series is recommended for all children 12 months to 12 years of age. Adults without acceptable presumptive immunity (e.g., born before 1980, serologic evidence of immunity, laboratory confirmation of disease, history of shingles, or documentation of previous immunization) should receive 2 doses of Varivax separated by at least 4 weeks. If there is a lapse of more than 4 weeks after the first dose, the second dose may be administered at any time without repeating the first dose. Varivax may be administered concurrently with other live viral vaccines, including **MMR-II** (Measles, Mumps, and Rubella Virus vaccine Live). If not given concurrently, at least 1 month should elapse between doses of 2 live vaccines.

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ASK PRN...

What are the exceptions to the rule that "all vaccines can be given together?"

According to the CDC, as a general rule, almost all vaccines can be administered at the same visit. However, there are some exceptions:

- **Prevnar 13** and **Menactra** vaccines should not be administered simultaneously to persons with functional or anatomic asplenia or HIV. When both Prevnar 13 and Menactra are indicated, Prevnar 13 should be administered first, followed by Menactra at least 4 weeks later.
- **Prevnar 13** and **Pneumovax 23** vaccines should not be administered at the same visit. When both Prevnar 13 and Pneumovax 23 are indicated, Prevnar 13 should be administered first, and Pneumovax 23 should be administered either at least 8 weeks later or at least 1 year later, depending on the age and health conditions of the recipient.
- The safety and efficacy of the administration of two adjuvanted vaccines (e.g., **Shingrix** and **Fluad**), either concomitantly or at other intervals, have not been evaluated.
- Two or more **live vaccines** may be administered together, but if not administered simultaneously, the vaccines should be separated by at least 4 weeks.

GOT QUESTIONS? WE HAVE ANSWERS!
Send your questions to us at:
questions@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 Pfizer, much in the news these days due to its COVID-19 vaccine, was founded in 1849 in the Williamsburg section of Brooklyn? Cousins Charles Pfizer and Charles Erhardt started the company with a $2,500 loan from Pfizer's father. A small brick building at the intersection of Harrison Avenue and Bartlett Street served as the company's first headquarters, where they manufactured the antiparasitic santonin. The company's early growth was driven by a process it developed to mass produce citric acid. Later, Pfizer would become a leader in the field of antibiotics, producing penicillin for the U.S. government during World War II, and developing tetracycline, doxycycline, azithromycin, Unasyn, and Zyvox, among others.

PHARMACY FUN

Since this issue has turned out to be mostly about vaccinations... and what else is there in pharmacy these days anyway?... we thought it appropriate to inject some immunization info into our quiz as well. Answer all the following clues and, using the first letter of each correct answer, spell the hidden word, which states what a vaccine does for infectious disease. The first reader to submit the correct answers to us at puzzle@prnnewsletter.com will win a $25 Amazon gift card.

1. **23-valent vaccine**
2. **German measles**
3. **"Father of immunology" (full name)**
4. **Precursor of Zoster**
5. **2 of 3 COVID-19 vaccines operate under this**
6. **Genus name of meningitis bacteria**
7. **aka lockjaw**
8. **Last name of either polio vaccine pioneer**

Answers to last month's ***PHARMACY FUN***:
1. Hydralazine 2. Omeprazole 3. Lidocaine 4. Isoxsuprine 5. Digoxin 6. Acyclovir 7. Yohimbine 8. Selegiline

References:
1. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid. Retrieved from www.fda.gov on 12/22/2021.