P.R.N.

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What's Inside…

FDA NEWS

FDA Investigating Suicide Reports with GLP-1 Agents

On January 11 of this year, the Food and Drug Administration disclosed that it has been evaluating reports of suicidal thoughts or actions in patients using GLP-1 receptor agonists (e.g., Ozempic, Trulicity, Victoza, Wegovy etc.). To date, the agency's preliminary evaluation has not found evidence that the use of GLP-1 drugs causes suicidal ideation, but the risk has not yet been definitively ruled out. FDA will continue to study this issue. The current labeling of GLP-1 drugs already contains information about the risk of suicidal thoughts or actions, but this is based upon reports of such events observed with some older medications used or tested for weight loss.

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

ZEPBOUND (Tirzepatide injection, solution).
Category: GLP-1/GIP receptor agonist.
Initial Dose: 2.5 mg once weekly.
MDD: 15 mg once weekly.

Eli Lilly and Company has received FDA approval for their new weight management drug Zepbound (Tirzepatide injection). Zepbound contains the same active ingredient as the company's **Mounjaro**, which is indicated for the treatment of type 2 diabetes mellitus. Zepbound is indicated for chronic weight management in adults with an initial BMI of 30 kg/m^2 or greater or a BMI of 27 kg/m^2 or greater in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes, obstructive sleep apnea, or cardiovascular disease). The recommended initial dose is 2.5 mg weekly; after 4 weeks, increase to 5 mg weekly. Dosage may be increased in 2.5 mg increments after at least 4 weeks on the current dose. Recommended maintenance doses are 5 mg, 10 mg, or 15 mg weekly. Administer once weekly at any time of day, with or without meals. Administer subcutaneously in the abdomen, thigh, or upper arm, and rotate sites with each dose.

The most common adverse reactions seen with Zepbound are nausea, diarrhea, vomiting, constipation, and abdominal pain. Zepbound contains a **black box** warning about dose– and treatment-duration-dependent thyroid C-cell tumors in rats. Zepbound is contraindicated in patients with a personal or family history of medullary thyroid cancer (MTC) and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

AIRSUPRA (Albuterol and Budesonide MDI).
Category: SABA/ICS Inhaler.
Initial Dose: 2 puffs by mouth as needed.
MDD: 6 doses (12 inhalations).

The FDA has approved a first-in-class metered dose rescue inhaler which combines a short-acting beta agonist (albuterol) with an inhaled corticosteroid (budesonide). Airsupra is indicated for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in adult patients with asthma. Each actuation delivers 90 mcg of albuterol and 80 mcg of budesonide. The recommended dose is 2 puffs by oral inhalation as needed for asthma symptoms. Patients should not exceed 6 doses (12 puffs) per day.

First Over-The-Counter Oral Contraceptive Pill Coming Soon

On July 13, 2023, the U.S. Food and Drug Administration announced approval of the first-ever nonprescription oral contraceptive. The active ingredient, Norgestrel, was first approved in 1973 and marketed by Pfizer under the brand name Ovrette, until its discontinuation ("for business reasons") in 2005. The OTC version, to be sold by Perrigo, will be called **Opill**. It is expected to be available early in 2024, and will be sold in pharmacies, convenience stores, and grocery stores, as well as online. Opill is a progestin-only contraceptive ("mini-pill") and must be taken at the same time every day. Counsel patients that if they are more than 3 hours late taking a dose, they must use a back-up method (condoms, etc.) every time they have sex during the next 2 days (48 hours). Patients may start taking Opill on any day of the month, and Opill should be taken every day continuously. Start each new month's pack without a break.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

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

The New York State Medicaid Program has updated the *Dispense Brand Name Drug when Less Expensive than Generic Program,* including 3 additions and 2 deletions:

Additions

Alphagan P 0.1%
Forteo
Votrient

Deletions

Flovent HFA
Pennsaid pump

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. Some of the more commonly prescribed drugs in the program include:

Advair Diskus
Advair HFA
Alphagan P 0.1%
Alphagan P 0.15%
Amitiza
Apriso
Azopt
Combigan
Daytrana
Depakote Sprinkle
Dexilant
Dymista
Epipen
Epipen Jr
Forteo
Glumetza
Kazano
Kombiglyze XR
Lialda
Nesina
NuvaRing
Onglyza
Pentasa
Pradaxa
Pylera
Renvela
Restasis
Retin-A cream
Spiriva Handihaler
Symbicort
Tegretol Susp
Tegretol XR
Trileptal Susp
Vascepa
Ventolin HFA
Votrient
Vyvanse capsules
Vyvanse chewable
Xopenex HF

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

New York State Expands Optometrists' Prescribing Authority

The New York State Board of Regents has adopted amendments to the Commissioner's regulations which will permit licensed optometrists in the state to prescribe specified oral therapeutic pharmaceutical agents to treat ocular diseases. Such prescribing was authorized by Chapter 506 of the Laws of 2021. As of October 25, 2023, optometrists who wish to prescribe the specified oral agents must apply to the State Education Department for certification to receive the "O" prescribing privilege. ("O" denotes an additional license certification of "ORT," indicating the practitioner has qualified for Oral ("O"), Therapeutic ("R"), and Diagnostic ("T") privileges.) The following chart summarizes all of the therapeutic pharmaceutical agents optometrists with the "O" privilege may prescribe:

Topical Therapeutic Agents

- Antibiotics
- Decongestants
- Anti-Allergy agents
- NSAIDs
- Steroids
- Anti-viral agents
- Hyperosmotic agents
- Cycloplegics
- Artificial tears
- Immunosuppressives

Topical Therapeutic Agents for Glaucoma

- Beta blockers
- Alpha agonists
- Direct-acting cholinergic agents
- Prostaglandin analogues
- Carbonic Anhydrase Inhibitors

Oral Therapeutic Agents

Antibiotics:

Augmentin
Azithromycin
Cephalexin
Doxycycline
Sulfa/Trimethoprim
Tetracycline

Antiglaucoma Agents:

Acetazolamide
Methazolamide

Antiviral Agents:

Acyclovir
Valacyclovir

Pharmacist-Administered Vaccine List Expanded

The list of vaccines which pharmacists may administer in New York State is contained in section 63.9 (a) (2) of the Commissioner's Regulations. The Respiratory Syncytial Virus (RSV) vaccine is not on that list, but pharmacists are permitted to administer RSV vaccine due to a determination letter issued by the Department of Health, in partnership with the State Education Department. This letter represents the first use of the power granted the Department by Chapter 555 of the Laws of 2021. The complete list of pharmacist-administered vaccines in New York State is contained below:

Influenza	**Measles, Mumps, Rubella**	**Varicella**
COVID-19	**Tetanus, Diphtheria, Pertussis**	**RSV**
Shingles	**Meningococcal**	**Hepatitis A**
Pneumococcal	**Human Papilloma Virus**	**Hepatitis B**

FEATURE ARTICLE...

REVIEW OF RSV VACCINES: ABRYSVO AND AREXVY

Since Gaining FDA approval last year, the RSV vaccines have become among the most popular immunizations in the community pharmacy setting. Some confusion has arisen, however , regarding the proper use of the two vaccines available, which are *not* interchangeable. A recent New York Times article documented more than 150 cases of patients who were administered the incorrect RSV vaccine. Both pharmacists and physicians were implicated in the errors, which included 128 pregnant women mistakenly given Arexvy, instead of Abrysvo, and 25 children under the age of 2 given the adult vaccine. The following side-by-side comparison of Abrysvo and Arexvy serves as a review of the approved indications and proper use of the two available RSV vaccines.

ABRYSVO

Indications: For the prevention of lower respiratory tract disease cause by Respiratory Syncytial Virus (RSV) in the following patient populations:

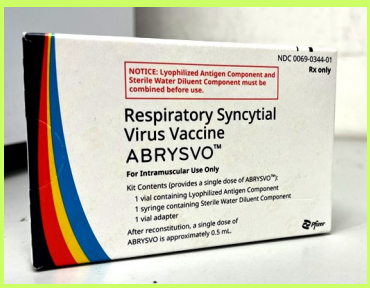
- **Pregnant women at 32 weeks 0 days through 36 weeks 6 days gestation from September through January in most of the continental United States.**
- **Individuals 60 years of age and older. People most likely to benefit from vaccination are those considered to be at increased risk for severe RSV disease, including patients with lung diseases, cardiovascular diseases, diabetes mellitus, neurologic or neuromuscular conditions, liver or kidney disorders, hematologic disorders, or severe immune compromise.**

Dosage and Administration: Administer a single dose (0.5 mL) intramuscularly. After reconstitution, administer Abrysvo immediately or store at room temperature and use within 4 hours.

Preparation: Abrysvo must be reconstituted before administration, resulting in a clear, colorless solution.

Description: Abrysvo contains recombinant RSV preF A and preF B antigenic components derived from genetically engineered Chinese hamster ovary cell lines.

Adverse reactions: The most common adverse reactions reported in pregnant individuals were: Injection site pain (40.6%), Headache (31%), Muscle pain (26.5%), and nausea (20%). In individuals 60 years of age and older, the most common adverse reactions reported were: Fatigue (15.5%), Headache (12.8%), Injection site pain (10.5%), and muscle pain (10.1%).



AREXVY

Indications: For the prevention of lower respiratory tract disease cause by Respiratory Syncytial Virus (RSV) in the following patient populations:

- **Individuals 60 years of age and older. People most likely to benefit from vaccination are those considered to be at increased risk for severe RSV disease, including patients with lung diseases, cardiovascular diseases, diabetes mellitus, neurologic or neuromuscular conditions, liver or kidney disorders, hematologic disorders, or severe immune compromise.** (Arexvy is NOT indicated for use in pregnant women due to an increased risk of preterm birth)

Dosage and Administration: Administer a single dose (0.5 mL) intramuscularly. After reconstitution, administer Arexvy immediately or store protected from light in the refrigerator or at room temperature and use within 4 hours.

Preparation: Arexvy is supplied in two vials that must be combined prior to administration. The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid.

Description: Arexvy contains recombinant RSVpreF3 as the antigen component, which is derived from genetically engineered Chinese hamster ovary cell lines. Arexvy also contains an adjuvant, $AS01_E$ to boost immune response. If possible, avoid co-administration with other adjuvanted vaccines (e.g., Fluad, Shingrix).

Adverse reactions: The most common adverse reactions reported were: Injection site pain (60.9%), Fatigue (33.6%), Myalgia (28.9%), Headache (27.2%), and Arthralgia (18.1%).

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ASK PRN...

Pharmacists in New York are now authorized to administer a number of childhood vaccines to adults, such as MMR and Gardasil. What are the recommended vaccination schedules for these vaccines in the adult population?

The dosing schedule for childhood vaccines in adults depends to some extent upon the patients previous immunization history, but here are the current ACIP guidelines for adults:

Measles, Mumps, and Rubella:

Adults with no evidence of immunity: 1 dose of MMR.

Students entering college or other post-secondary educational institutions with no evidence of immunity: 2 doses of MMR at least 4 weeks apart if no previous dose of MMR

Health care personnel with no evidence of immunity: 2 doses of MMR at least 4 weeks apart.

Gardasil:

Age 15 or older at initial vaccination: 3 dose series at 0, 2 months, and 6 months.

Adults who received 1 dose between ages 9 and 14: 1 additional dose completes series.

Varicella:

Adults with no evidence of immunity: 2 doses 4 to 8 weeks apart.

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 leukotriene receptor antagonist **Montelukast** was named, in part, for the city in which it was developed? After the structure of leukotrienes was discovered in 1979, Merck initiated a program to find drugs which would act on the receptor for this inflammatory mediator. The work, which resulted in the production of Singulair, was done at the Merck Frosst facility in Montreal, Canada, hence the name, *Mont*elukast[1]. For the story of another drug named for its place of origin, see the *Did You Know?* section of the very first issue of ***PRN***, Volume 1, #1, available in the ARCHIVE section of our website, *www.prnnewsletter.com*.

PHARMACY FUN

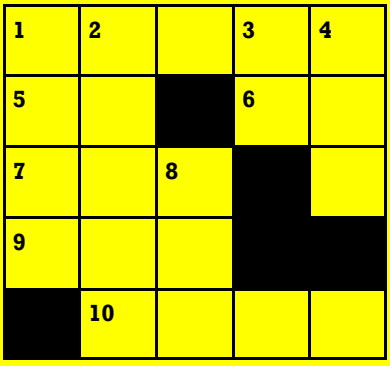
It's crossword puzzle time again here at *Pharmacy Fun*! The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a $25 gift card from Amazon.

Across:

1. Umeclidinium/Vilanterol
5. Both ears
6. Nurse who can prescribe
7. Normal cardiac finding
9. Requires proper ID
10. They can be found on an ambulance

Down:

1. Organization that offers Medicare D plans
2. Ratched, for one
3. Abbreviation for person in 2 Down
4. Agency pharmacists never want to hear from
8. Sleep phase



Answers to last issue's ***PHARMACY FUN***:
1. Louis Pasteur 2. Gaston Ramon 3. Jonas Salk 4. Albert Sabin 5. Leila Denmark
6. Louis Pasteur 7. Gaston Ramon 8. Albert Calmette

References:
1. Li, Jie Jack. *Laughing Gas, Viagra, and Lipitor: The Human Stories Behind the Drugs We Use.* Oxford University Press, 2006.