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What's Inside…

FDA NEWS

FDA Adds Boxed Warning to Uloric Label

Following an in-depth review of the results of a safety clinical trial, the Food and Drug Administration (FDA) has concluded that there is an increased risk of death with the use of **Uloric** (febuxostat) when compared to allopurinol, another medication used for gout. As a result, the agency is updating the Uloric prescribing information to require a **black box warning**, the most serious alert the FDA issues on drug labels. In addition, the approved use of Uloric will now be limited to certain patients who are not treated effectively, or experience severe side effects, with allopurinol. A new patient medication guide will also be issued. In the study cited by the FDA, more than 6000 patients were treated with either Uloric or allopurinol, and followed for 7 years. The results showed an increase in heart-related deaths (15 per 1000 vs. 11 per 1000) and death from all causes (26 per 1000 vs. 22 per 1000) in the Uloric-treated patients. Health care professionals are being advised to reserve Uloric for patients who have failed or can not tolerate maximally titrated allopurinol doses, and to monitor for cardiovascular signs and symptoms in patients who are taking Uloric.

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JATENZO (Testosterone undecanoate).
Category: Oral androgen.
Initial Dose: 237 mg twice daily.
MDD: 396 mg twice daily.

Clarus Therapeutics has received FDA approval to market Jatenzo, a new, oral form of testosterone. Jatenzo is indicated for testosterone replacement therapy in adult males with conditions associated with a deficiency or absence of endogenous testosterone. Jatenzo will carry a **black box warning** regarding increases in blood pressure. Prior to initiating therapy with Jatenzo, a diagnosis of hypogonadism should be confirmed with serum testosterone level measurements on at least 2 separate days. The starting dose of 237 mg twice a day may be adjusted to a minimum of 158 mg twice daily or a maximum of 396 mg twice daily. Wait at least 7 days after starting treatment to titrate dose.

SUNOSI (Solriamfetol).
Category: Dopamine and norepinephrine reuptake inhibitor.
Initial Dose: 75 mg once daily for narcolepsy; 37.5 mg once daily for obstructive sleep apnea.
MDD: 150 mg once daily.

Jazz Pharmaceuticals has announced that the FDA has approved Sunosi, a dopamine and norepinephrine reuptake inhibitor (DNRI), which is indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). Sunosi should be administered once daily upon awakening, and should not be given within 9 hours of bedtime because of the potential to interfere with sleep. Dosage may be increased at intervals of at least 3 days to a maximum of 150 mg once daily.

ROCKLATAN (Netarsudil and latanoprost ophthalmic solution).
Category: Anti-glaucoma combination agent.
Initial Dose: One drop in affected eye(s) once daily in the evening.
MDD: One drop in affected eye(s) once daily in the evening.

The FDA has approved a new fixed-dose combination agent for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or intraocular hypertension. Aerie Pharmaceuticals' Rocklatan is a combination of the Rho kinase inhibitor netarsudil (Rhopressa) and the prostaglandin analogue latanoprost (Xalatan). Use of Rocklatan can cause hyperpigmentation of the iris and increased length, thickness and number of eyelashes. The recommended dose is one drop in the affected eye(s) once daily in the evening.

DOVATO (Dolutegravir and lamivudine).
Category: Anti-HIV combination agent.
Initial Dose: One tablet once daily with or without food.
MDD: One tablet once daily with or without food.

ViiV Healthcare has been granted FDA approval for Dovato, a fixed-dose combination of the integrase strand transfer inhibitor dolutegravir and the nucleoside analogue reverse transcriptase inhibitor lamivudine. Dovato is indicated as a complete regimen for the treatment of HIV-1 infection in adults with no antiretroviral treatment history, making Dovato the first complete, single-tablet, two-drug regimen for treatment-naïve adults. The recommended dose is one tablet taken once daily with or without food. If coadministered with carbamazepine or rifampin, an additional daily dose of dolutegravir 50 mg is needed.

Lilly to Offer Half-Priced Humalog Insulin through Authorized Generic

Eli Lilly and Company have announced that they will begin offering an authorized generic version of their best-selling insulin product, Humalog, at 50 percent of the price of the branded version. The move comes in response to a series of high-profile congressional hearings into drug pricing in the United States. The authorized generic, which is identical to the original in every respect except the packaging, will have a list price of $137.35 per vial and $265.20 for a pack of 5 KwikPens. In a related action, taken just a few hours before a recent House committee hearing on insulin prices, Sanofi, maker of Lantus, announced a program which will allow patients to purchase up to 10 vials of insulin or 10 boxes of insulin pens for just $99.00 per month. The offer is an expansion of the company's already existing Insulins Val*you* Savings Program, and the new pricing will take effect in June. The savings can be applied to prescriptions for Admelog, Apidra, Toujeo, and Lantus insulins vials or pens (the combination product, Soliqua, is not included in the savings program).

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Reminder on Proper Use of the OPRA Physician Override

The New York State Medicaid Program has issued a reminder bulletin regarding the allowable use of the OPRA override for the "non-matched prescriber ID" rejection.

A provision of the Affordable Care Act and federal regulations require enrollment of physicians and other health professionals whenever ordering/prescribing/referring/ attending (OPRA) services are provided under Medicaid. When billing for a prescription written by a non-enrolled provider, the pharmacist will receive rejection code **56: "NON-MATCHED PRESCRIBER ID."** There is an OPRA override for this rejection, however this override is *only to be used for non-licensed prescribers*, such as unlicensed interns, residents, and foreign physicians in training. Use of the override for non-enrolled licensed physicians is no longer permitted and may result in recovery of any payments made to the pharmacy. Although it is sometimes unclear from hospital prescriptions if the prescriber is licensed, pharmacists should note that any prescriber who has a New York State license number and/or their own DEA number (without a hospital suffix) is NOT eligible for the OPRA override. The only option when your pharmacy is presented with a prescription written by a licensed, non-enrolled provider for a Medicaid member is to **obtain a new prescription from an enrolled provider**.

In the case of unlicensed physicians (interns, residents, etc.), the OPRA override codes are as follows:

Reason for Service Code: PN (Prescriber consultation)

Result of Service Code: 3H (Follow up/report)

Submission Clarification Code (also known as the Drug Prescription Override Field)**: 02** (Other override)

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Health Commissioner Renews Blanket Waiver of Electronic Prescribing Requirements

Howard A. Zucker, New York State Commissioner of Health, has issued a letter, dated February 21, 2019, renewing the blanket waiver of the electronic prescribing requirements in the Education Law (§ 6810) for certain exceptional circumstances in which electronic prescribing is not feasible. The waiver addresses situations in which software limitations preclude transmission of all the required information on a prescription, such as in the case of a mixture of ingredients to be compounded by a pharmacist. The blanket waiver of electronic prescribing is reevaluated by the Department of Health yearly; the current waiver will be in effect from March 25, 2019 to March 24, 2020. The 10 exceptional circumstances for which the electronic prescribing requirement is waived are as follows:

1. **Any practitioner prescribing a controlled or non-controlled substance, containing two (2) or more products, which is compounded by a pharmacist.**
2. **Any practitioner prescribing a controlled or non-controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.**
3. **Any practitioner prescribing a controlled or non-controlled substance that contains long or complicated directions.**
4. **Any practitioner prescribing a controlled on non-controlled substance that requires a prescription to contain certain elements required by the federal Food and Drug Administration (FDA) that are not able to be accomplished with electronic prescribing.**
5. **Any practitioner prescribing a controlled on non-controlled substance under approved protocols for expedited partner therapy, collaborative drug therapy management or comprehensive medication management, or in response to a public health emergency that would allow a non-patient specific prescription.**
6. **Any practitioner issuing a non-patient specific prescription for an opioid antagonist.**
7. **Any practitioner prescribing a controlled on non-controlled substance under a research protocol.**
8. **A pharmacist dispensing controlled and non-controlled substance compounded prescriptions, prescriptions containing long or complicated directions, and prescriptions containing certain elements required by the FDA or any other governmental agency that are not able to be accomplished with electronic prescribing.**
9. **A pharmacist dispensing prescriptions under a research protocol, or under approved protocols for expedited partner therapy, or for collaborative drug management or comprehensive medication management.**
10. **A pharmacist dispensing non-patient specific prescriptions, including opioid antagonists, or prescriptions issued in response to a declared public health emergency.**

Prescriptions issued under any of the above-listed circumstances may be written on the Official New York State Prescription Form, or may be called in to a pharmacist as an oral prescription. Keep in mind that any oral prescription for a controlled substance must conform to the regulations regarding emergency prescriptions for controlled substances (e.g., no more than a 5 day supply if used in accordance with directions for use). The Commissioner's letter affirms the fact that pharmacists in New York State may continue to dispense prescriptions written on the Official New York State Prescription Form, and oral prescriptions, under this waiver.

FEATURE ARTICLE...

Ellipta Inhalers: Clearing The Air

In May of 2013, the FDA approved GSK's **Breo Ellipta**, a new, once-daily inhaler indicated for both COPD and asthma. This was followed, in quick succession, by 4 more once-daily "Ellipta" inhalers: **Anoro**, **Incruse**, **Arnuity**, and, most recently, **Trelegy**. While all 5 inhalers have received high marks for ease of use and once-daily convenience, the naming of the inhalers has been less well received. The Institute for Safe Medicine Practices (ISMP) has documented over 500 error reports involving Ellipta inhalers in the span of just one year, revealing the fact that both patients and healthcare providers have been confused by these products. The use of the name Ellipta for all of the products, as well as similar packaging, have been cited as causes of these errors. In an effort to clear up the confusion, we offer the following chart which highlights the differences between the 5 Ellipta inhalers.

PRODUCT NAME (Drug Categories)	**Active Ingredients and Package Size**	**Indicated for Asthma**	**Indicated for COPD**	**Recommended Daily Dose**	**Clinical Notes**
ANORO ELLIPTA (ACh + LABA) 	Umeclidinium 62.5 mcg and Vilanterol 25 mcg Package size = 60 blisters (30 doses)		✓	*Maintenance treatment of COPD:* 1 oral inhalation once daily	May worsen narrow-angle glaucoma May worsen urinary retention Do not use to treat acute symptoms
ARNUITY ELLIPTA (ICS) 	Fluticasone furoate (available in 50 mcg, 100mcg, and 200 mcg strengths) Package size = 30 blisters (30 doses)	✓		*Treatment of asthma:* *12 years and older:* 1 oral inhalation of 100 mcg or 200 mcg once daily *5 to 11 years old:* 1 oral inhalation of 50 mcg once daily	Advise patient to rinse his/her mouth with water without swallowing after inhalation to prevent fungal infection of mouth Do not use to treat acute symptoms
BREO ELLIPTA (ICS + LABA) 	Fluticasone furoate and Vilanterol (available in 100 mcg/25 mcg and 200 mcg/25 mcg strengths) Package size = 60 blisters (30 doses)	✓	✓	*Maintenance treatment of COPD:* 1 oral inhalation of 100/25 once daily *Treatment of Asthma:* *18 years and older* 1 oral inhalation of 200/25 once daily	Advise patient to rinse his/her mouth with water without swallowing after inhalation to prevent fungal infection of mouth Do not use to treat acute symptoms
INCRUSE ELLIPTA (ACh) 	Umeclidinium 62.5 mcg Package size = 30 blisters (30 doses)		✓	*Maintenance treatment of COPD:* 1 oral inhalation once daily	May worsen narrow-angle glaucoma May worsen urinary retention Do not use to treat acute symptoms
TRELEGY ELLIPTA (ICS + LABA + ACh) 	Fluticasone furoate 100 mcg Umeclidinium 62.5 mcg and Vilanterol 25 mcg Package size = 60 blisters (30 doses)		✓	*Maintenance treatment of COPD:* 1 oral inhalation once daily	May worsen narrow-angle glaucoma May worsen urinary retention Advise patient to rinse his/her mouth with water without swallowing after inhalation to prevent fungal infection of mouth Do not use to treat acute symptoms

ACh = Anticholinergic LABA = Long-Acting Beta$_2$-Adrenergic Agonist ICS = Inhaled Corticosteroid

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ASK PRN...

Our pharmacy still receives written prescriptions from a number of prescribers. Which practitioners are exempt from mandatory electronic prescribing, and is the pharmacist responsible for verifying such exemptions?

The New York State Department of Health (DOH) has confirmed that pharmacists are ***NOT*** required to verify that a practitioner falls under one of the exemptions from the requirement to electronically prescribe. Pharmacists may continue to dispense medications from valid written, oral, or fax prescriptions that are consistent with current laws and regulations. In addition to the recently renewed blanket waiver issued by DOH (see Pharmacy Law on page 2 of this issue), the Department has published the following list of exceptions to mandatory electronic prescribing:

- **Prescriptions written by veterinarians, who are excluded from electronic prescribing.**
- **Prescriptions issued in circumstances where electronic prescribing is not available due to temporary technological or electrical failure.**
- **Prescriptions issued by practitioners who have received a waiver from the Department of Health.**
- **Prescriptions issued under circumstances where the practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, *and* such delay would adversely impact the patient's medial condition. In addition to these circumstances, if the prescription is for a controlled substance the quantity cannot exceed a 5 day supply if used in accordance with the directions for use.**

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 first person to receive insulin treatment was a 14-year-old Canadian boy named Leonard Thompson? Thompson, weighing only 65 pounds and near death, was brought to Toronto General Hospital in January 1922, where his father consented to allow the experimental treatment by a young surgeon named Frederick Banting[1]. The crude insulin formulation, extracted from dogs, saved the boy's life and revolutionized the treatment of diabetes. Thompson lived another 13 years, and Banting and his associates went on to win the Nobel Prize for Medicine in 1923.

PHARMACY FUN

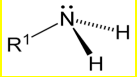
Back by popular demand, it's rebus time again! Be the first to decipher the following picture puzzles and win a set of PRN stylus pens (hint: all of the correct answers are common OTC medications). Send your answers to us at *puzzle@prnnewsletter.com*.

1. 5,280 Feet +  + a

2.  + 

3.  +  +  + N

4.  + $\sqrt{1936}$

5. 3 Scruples + 

6.  + 

Answers to last month's ***PHARMACY FUN***:
Across: 1. Opium 5. DO 6. DM 7. OPD 9. RPh 10. Yale
Down: 1. Odor 2. Poppy 3. UD 4. MME 8. DHA

References:
1. Markel, Howard, MD. "How a boy became the first to beat back diabetes." *PBS News Hour*. Accessed 4/16/19 at: www.pbs.org/newshour/health