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What's Inside…

FDA NEWS

Norpramine Safety Warning

The FDA's MedWatch website has issued a safety alert regarding the tricyclic antidepressant **Norpramine** (desipramine). The warning states that extreme caution should be used when prescribing the drug to patients with a family history of sudden death, cardiac dysrythmias, and cardiac conduction disturbances. It is also noted that some patients may have seizures before cardiac dysrythmias and death and that desipramine overdose is more likely to result in death than overdose with other tricyclic antidepressants. In a letter to healthcare professionals from drug maker Sanofi-Aventis, revisions of the prescribing information were outlined, including the following changes made to the **OVERDOSAGE** section:

Management, Gastrointestinal Decontamination: Activated charcoal should be administered to patients who present early after an overdose.

Management, Cardiovascular: Serum alkalinization with IV sodium bicarbonate and hyperventilation (as needed) should be instituted in patients manifesting significant toxicity, such as QRS widening.

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

New Treatment for Cyclic Bleeding: Xanodyne Pharmaceuticals has received FDA approval for **Lysteda** (tranexamic acid), a new non-hormonal treatment for women suffering from cyclic heavy menstrual bleeding (menorrhagia). Lysteda is a synthetic lysine amino acid derivative which diminishes the dissolution of hemostatic fibrin by plasmin. In clinical trials, the most commonly reported adverse effects were headache, sinus and nasal symptoms, back pain, abdominal pain, musculoskeletal pain, joint pain, muscle cramps, migraine, anemia, and fatigue. Lysteda is contraindicated in women with active thromboembolic disease, or a history or intrinsic risk of thrombosis or thromboembolism. Patients should be advised to discontinue Lysteda immediately if visual or ocular symptoms occur. Women using hormonal contraceptives should use Lysteda only if there is a strong medical need and the benefit of treatment will outweigh the potential increased risk of a thrombotic event. The recommended dose of Lysteda is 1300 mg (two 650 mg tablets) three times a day for a maximum of 5 days during monthly menstruation.

Zegerid OTC: Merck & Co. announced that the FDA has approved **Zegerid OTC** (omeprazole 20 mg/sodium bicarbonate 1100 mg) for over-the-counter treatment of frequent heartburn (Zegerid 40 mg will remain prescription only). Zegerid OTC is a 14-day course of treatment taken once per day to treat frequent heartburn. The product will be marketed by Schering-Plough, a division of Merck & Co., and will be available in pharmacies in the first half of 2010.

Needle-Free Injection for Migraine: Zogenix, Inc. has been granted FDA approval to market **Sumavel DosePro** (sumatriptan succinate injection), a new needle-free injectable form of sumatriptan indicated for the treatment of acute migraine attacks, with or without aura, and the acute treatment of cluster headache episodes. Sumavel DosePro uses pressure from compressed nitrogen, rather than a needle, to deliver a subcutaneous dose of medication, although the prescribing information reveals that there is actually a *higher incidence* of injection site reactions with Sumavel than with the standard sumatriptan injection (e.g., Imitrex injection).[1] Patients should be counseled to inject Sumavel into a clean, dry area of the abdomen or thigh. Sumavel *should not* be injected into the arm, should not be injected through clothes, and should not be injected into moles or scars, or within 2 inches of the navel.

Changes to Diclofenac Labeling: Due to post-marketing reports of drug-induced hepatotoxicity, the FDA has requested that manufacturers of diclofenac-containing products, including **Voltaren Gel**, update their prescribing information. The revision states that a higher incidence of borderline, moderate, and marked elevations of ALT or AST was observed in patients receiving diclofenac, when compared to other NSAIDs. Cases have been reported in the first month, and in some cases, the first 2 months of therapy, but can occur at any time during treatment. Physicians are advised to monitor transaminases periodically in patients receiving long-term therapy with diclofenac.

McNeil Recalls All Lots of Tylenol Arthritis Pain with EZ-Open Cap

The makers of Tylenol, McNeil Consumer Healthcare, have announced a recall of all available lots of **Tylenol Arthritis Pain Caplet 100 count bottles with the distinctive red EZ-OPEN CAP**. This total recall follows an initial limited recall of 5 lots of the product in November, 2009. The recall was initiated after the company received reports of an unusual moldy, musty, or mildew-like odor that was associated with nausea, stomach pain, vomiting, and diarrhea. The odor was caused by trace amounts of a chemical called 2,4,6-tribromoanisole, which is believed to have resulted from the breakdown of a chemical used to treat the wooden pallets that transport and store the packaging materials for the Tylenol product. Customers who purchased Tylenol Arthritis Pain Caplet 100 count with red EZ-OPEN CAP are instructed to stop using the product immediately and contact McNeil for instructions on a refund or replacement. McNeil may be reached at **1-888-222-6036** Monday-Friday 8 AM to 8 PM Eastern Time and Saturday-Sunday 9 AM to 5 PM Eastern Time. In addition, adverse reactions may also be reported to the FDA's MedWatch Program at ***www.fda.gov/medwatch*** or by fax at **1-800-FDA-0178**.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Additions to the Mandatory Generic Program

Effective December 1, 2009, several additions have been made to the Mandatory Generic Drug Program. As of that date, prescriptions written for the following **brand name** drugs will require prior authorization:

Bleph-10 ophthalmic drops
Fioricet/Codeine capsules
Keppra tablets
Keppra oral solution
Lamictal tablets
Lamictal dispersible tablets
Neocidin ophthalmic drops
Nitro-Dur patches
Pamine 2.5 mg tablets
Pamine Forte 5 mg tablets
Vicodin 5/500 mg tablets
Wellbutrin XL 150 mg tablets
Zantac 15 mg/mL syrup
Zerit 1 mg/mL solution
Zerit capsules

Practitioners wishing to prescribe any of these brand-name products must call the Prior Authorization Call Line at **1-877-309-9493** and document the 11-digit authorization number on the prescription. Pharmacists filling such prescriptions are also required to call the number above to validate the authorization before filling the prescription.

Change in Billing for Emergency Contraception

The New York State Medicaid Program has changed the procedure for billing emergency contraceptives without a prescription. Effective immediately, dual-labeled emergency contraceptives can be dispensed to Medicaid-eligible females *17 years of age and older* without a prescription. In addition, the "dummy" prescriber ID formerly used for billing such transactions *is no longer required*. The following products are covered for this purpose:

Plan B
Plan B One-Step
Next Choice

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Review of Regulatory Changes in 2009

In 2009, relatively few major changes were enacted in pharmacy regulations, although there are several updates to report from each of the agencies that regulate pharmacy in New York State.

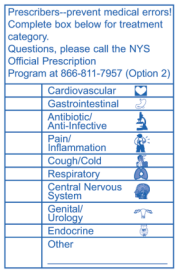
New York State Board of Pharmacy

A number of changes made to the Regent's Rules (29.7) and the Commissioner's Regulations (63.3 and 63.6) took effect on August 19, 2009. They include:

- **Oral prescriptions may be stored in electronic, rather than written, form, as long as they contain the electronic equivalent of the signature or readily identifiable initials of the pharmacist receiving the oral order**
- **Electronically transmitted prescriptions may be stored as a permanent and secure electronic record in lieu of printing out a hard copy**
- **An electronic record of all prescriptions filled and refilled each day, signed electronically by the pharmacist(s) whose initials appear on the record, can be kept instead of printing out a daily register hard copy**
- **As an alternative to taking Part III of the New York State pharmacy licensure examination (the compounding and pharmacy practice exam), candidates may submit certification of competency received through an approved residency program in pharmacy practice (such certification shall be completed by the residency program director)**

New York State Bureau of Narcotic Enforcement

The New York State Department of Health revised the Official New York State Prescription to include a patient safety feature (see image at right). In an effort to decrease medication errors, a check box featuring 9 treatment categories was added, which allows the prescriber to communicate to the pharmacist the general purpose for which the prescription was written. The utilization of the check box is optional, but strongly encouraged. Since completion of the check box by the prescriber is not mandatory, prescriptions may still be filled even if the check box has not been used.


Prescribers--prevent medical errors!
Complete box below for treatment category.
Questions, please call the NYS Official Prescription Program at 866-811-7957 (Option 2)

- Cardiovascular
- Gastrointestinal
- Antibiotic/ Anti-Infective
- Pain/ Inflammation
- Cough/Cold
- Respiratory
- Central Nervous System
- Genital/ Urology
- Endocrine
- Other

The Bureau of Narcotics has also clarified an issue pertaining to information required on prescriptions issued for controlled substances. Regulations require that such prescriptions contain the address of the ultimate user, and the Bureau has stated that a post office box *is not an acceptable address*. In cases where a P.O. Box is used, pharmacists must obtain the ultimate user's actual street address. Pharmacists are not required to obtain the prescriber's authorization to add this information to the prescription if the information is obtained through a good-faith effort.

The Food and Drug Administration (FDA)

The FDA published a rule on prescription drug labeling, which took effect on July 1, 2009. The rule states that every new and refill prescription dispensed by pharmacies must contain the following statement:

Call your doctor for medical advice about side effects.
You may report side effects to the FDA at 1-800-FDA-1088.

This rule may be complied with by attaching a sticker containing the statement to the package, vial, or container, by printing the statement on the prescription vial cap, by distributing the statement on a separate piece of paper, by including the statement in consumer medical information, or by providing an FDA-approved Medication Guide containing the statement.

Feature Article..

REVIEW OF NEW DRUGS OF 2009

As 2009 draws to a close, and as various year-end "top ten" lists clutter newspapers, magazines, television shows, and blogs everywhere, we thought we'd come up with a list of our own — the leading new drugs introduced during the past 12 months. In 2009, the FDA approved 25 new molecular entities (NMEs), defined as drugs containing active ingredients never before approved in the U.S. That represents a slight improvement over 2008, but is still substantially less than the totals approved in the 1990s (in 1998 alone, nearly 60 NMEs were approved). For our "top six" list, we have chosen those agents most likely to be encountered in the community pharmacy, thereby necessarily omitting some important new drugs that are used primarily in the hospital setting or physician's office.

Effient (prasugrel)

Indication: Effient is a platelet inhibitor indicated for the reduction of thrombotic events in patients with acute coronary syndrome who are to be managed with angioplasty

Contraindications: Active pathological bleeding, prior transient ischemic attack or stroke

Adverse effects: Bleeding, including life-threatening and fatal bleeding, is the most commonly reported adverse reaction

Dosage: Initiate treatment with a single 60 mg oral loading dose. Continue at 10 mg once daily with or without food (consider 5 mg once daily for patients <60 kg). Patients should also take aspirin (75 mg to 325 mg) daily

Strengths available: 5 mg and 10 mg tablets

Livalo (pitavastatin)

Indication: Livalo is a HMG-CoA reductase inhibitor indicated for patients with primary hyperlipidemia and mixed hyperlipidemia

Contraindications: Pregnancy, breastfeeding, active liver disease, co-administration with cyclosporine

Adverse effects: Myalgia, back pain, diarrhea, constipation, and extremity pain were the most frequently encountered adverse reactions

Dosage: The initial dose is 2 mg once daily, taken with or without food, at any time of day. The maximum daily dose is 4 mg. For patients with moderate renal impairment and end-stage renal disease on hemodialysis the starting dose is 1 mg (maximum 2 mg)

Strengths available: 1 mg, 2 mg, and 4 mg tablets

Multaq (dronedarone)

Indication: Multaq is an antiarrhythmic drug indicated to reduce hospitalization in patients with paroxysmal or persistent atrial fibrillation or atrial flutter

Contraindications: Class IV heart failure or symptomatic heart failure with a recent decompensation, 2nd or 3rd degree atrioventricular (AV) block, bradycardia <50 bpm, concomitant use of strong CYP3A inhibitor or drugs or herbal products which prolong the QT interval, severe hepatic impairment

Adverse effects: Diarrhea, nausea, abdominal pain, vomiting and asthenia

Dosage: 400 mg twice a day with morning and evening meals

Strengths available: 400 mg tablets

Onglyza (saxagliptin)

Indication: Onglyza is a dipeptidyl pepdidase-IV (DPP-IV) inhibitor indicated for adults with type 2 diabetes mellitus.

Contraindications: Hypersensitivity to any component of the formulation

Adverse effects: Headache, increased reports of peripheral edema in patients also taking a thiazolidinedione, increased reports of hypoglycemia in patients also taking a sulfonylurea

Dosage: The recommended dose is 2.5 mg or 5 mg once daily taken regardless of meals. A dose of 2.5 mg is recommended for patients with moderate or severe renal impairment and for those taking CYP3A4/5 inhibitors

Strengths available: 2.5 mg and 5 mg tablets

Savella (milnacipran)

Indication: Savella is a selective serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the management of fibromyalgia in adults

Contraindications: Use of monoamine oxidase inhibitors (MAOIs) concomitantly or in close temporal proximity. Use in patients with uncontrolled narrow-angle glaucoma

Adverse effects: Nausea, headache, constipation, dizziness, insomnia, hyperhidrosis, palpitations, dry mouth

Dosage: Titrate as follows:
Day 1: 12.5 mg once
Days 2-3: 12.5 mg twice daily
Days 4-7: 25 mg twice daily
After Day 7: 50 mg twice daily
Maximum daily dose is 200 mg

Strengths available: 12.5 mg, 25 mg, 50 mg, and 100 mg tablets

Uloric (febuxostat)

Indication: Uloric is a xanthine oxidase inhibitor indicated for the chronic management of hyperuricemia in patients with gout

Contraindications: Uloric is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline

Adverse effects: Liver function abnormalities, nausea, arthralgia, rash. A higher rate of cardiovascular thromboembolic events has been observed in patients taking Uloric than in those taking allopurinol

Dosage: The recommended starting dose is 40 mg once daily without regard to food. If needed, the dose may be increased to 80 mg once daily

Strengths available: 40 mg and 80 mg tablets

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ASK PRN...

When calling in a prescription for a controlled substance, is the prescriber required to supply the pharmacist with the serial number from the Official New York State Prescription?

No. As the Bureau of Narcotics pointed out in their Summer 2009 newsletter (go to ***www.health.state.ny.us/professionals/narcotic***), prescribers are not required to provide pharmacists with the serial number when phoning in a prescription. In fact, even if the prescriber does supply the serial number, the pharmacist *should not* use that number when submitting data to the Bureau of Narcotics: pharmacists should always indicate that a prescription is an orally prescribed controlled substance by entering the number "9" eight times in the serial number field. When the follow-up hard copy prescription is received, pharmacists *should not* edit the prescription to reflect the serial number on the hard copy.

Are pharmacists *required* to honor all requests for refill transfers?

No. Section 63.6(a)(8) reads: "pharmacists at registered pharmacies ***may***, at the express request and approval of a patient or a person authorized to act on behalf of the patient, transfer prescription information to, or accept a transfer from, another registered pharmacy." Examples of legitimate reasons for refusing a refill transfer include: if, in the professional judgment of the pharmacist, the transfer would not be in the best interest of, or would be harmful to, the patient's health and/or if the pharmacist believes that the transfer involves intentional abuse or deception.

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 all three of the gifts of the Magi— gold, frankincense, and myrrh— have pharmacological properties and are still used today for medicinal purposes? In fact, one of them even requires a prescription! The Three Kings, most often identified as Caspar, Melchior, and Balthasar, dispensed a topical antiseptic and astringent (myrrh), an anti-inflammatory (frankincense), and an anti-rheumatic agent (gold). Gold salts are available by prescription under the brand name **Ridaura** (auranofin), which is indicated for the management of active classical or definite rheumatoid arthritis in patients who have not benefited from, or are intolerant of, an adequate trial of full doses of one or more nonsteroidal anti-inflammatory drugs (NSAIDs).

PHARMACY FUN

This month's puzzle comes from our perplexed pharmacy student file. It seems that three of the aforementioned undergrads were working jointly on a research project involving the storage of drugs under extreme conditions, such as on a future space mission. Each day for a month they dutifully recorded the decreasing temperatures, both Celsius and Fahrenheit, in their simulated space capsule and the corresponding physical changes in the drug samples. On the final day of the semester, the first student to arrive noticed that both the Celsius and Fahrenheit thermometers displayed the exact same temperature! Realizing there had been a failure in one of the devices, the student threw up his hands and determined to start all over next year. The next student did likewise, but when the third student arrived and saw the very same readings, he recorded them, finished the report, and handed it in, receiving an A+. What did the third student know that the first two didn't, and, for extra credit, what temperature did the thermometers read? The first reader to submit the correct answer to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

Answers to last month's **PHARMACY FUN**:
1. Spironolactone 2. Cimetidine 3. Chlorpromazine 4. Indomethacin 5. Eflornithine 6. Metformin (Pioglitazone and Rosiglitazone, too!) 7. Propranolol 8. Demeclocycline

References:
1. Sumavel DosePro [package insert]. San Diego, CA: Zogenix, Inc.; September, 2009.