P.R.N.

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What's Inside…

TUSSIONEX ALERT

The FDA has issued an alert regarding the misuse and/or inappropriate use of UCB's **Tussionex Pennkinetic Extended-Release Suspension®**. Tussionex contains hydrocodone 10 mg and chlorpheniramine 8 mg per 5 mL. ***The maximum adult dose is one teaspoonful every 12 hours*** (*1/2 teaspoonful every 12 hours for children 6 to 12 years old*). Reports of life-threatening adverse effects and death have revealed physicians prescribing, and patients taking, inappropriate doses (giving more than 1 teaspoonful per dose or giving more frequently than every 12 hours). In some cases, Tussionex was prescribed or given to children less than 6 years old and was associated with reports of patient deaths. The FDA also recommends that Tussionex always be measured with an oral syringe or other calibrated device to avoid accidental overdose when using household spoons. Patients should be instructed to call their doctor immediately if they experience difficulty breathing, slow heartbeat, severe sleepiness, or cold, clammy skin. The manufacturer has agreed to update the product labeling to reflect these safety concerns, with special emphasis on accurate dosing and age-appropriate prescribing.

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

Nexium Approved for Children: AstraZeneca has received FDA approval for short-term use of **Nexium** (esomeprazole magnesium) in children aged 1 to 11 years. This represents the third proton pump inhibitor to receive pediatric approval (the other two are **Prilosec** [omeprazole] and **Prevacid** [lansoprazole]) Nexium is indicated in pediatric patients for the treatment of gastroesophageal reflux disease (GERD), an increasingly common diagnosis in children. Adverse reactions most commonly seen in pediatric patients (≥1-2%) include headache, diarrhea, abdominal pain, nausea, and somnolence. In addition to 20 mg and 40 mg capsules, Nexium will be supplied in powder packets for oral suspension in 10, 20, and 40 mg strengths. The contents of one packet should be emptied into a container holding 1 tablespoonful (15 mL) of water, Stir, then leave for 2 to 3 minutes to thicken. Stir again and drink within 30 minutes.[1] The recommended pediatric dose is outlined below:

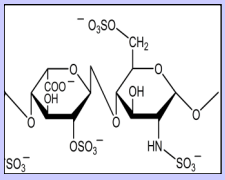
Nexium Pediatric Dosing

Indication	Dose	Duration of Tx
Symptomatic GERD	10 mg	QD for up to 8 weeks
Erosive Esophagitis (<20 kg)	10 mg	QD for 8 weeks
Erosive Esophagitis (≥20 kg)	10-20 mg	QD for 8 weeks

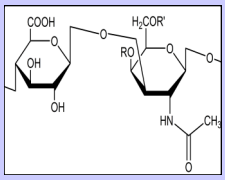
New Antidepressant: Wyeth Pharmaceuticals has been granted approval to market **Pristiq** (desvenlafaxine) for the treatment of major depressive disorder in adult patients. As its chemical name suggests, Pristiq is the desmethyl metabolite of venlafaxine (Wyeth's **Effexor**). Unlike Effexor, however, which should be taken with food, Pristiq may be given without regard to meals. The recommended dose is 50 mg once daily. Pristiq is an extended-release tablet and should NOT be divided, crushed, chewed, or dissolved. In short-term studies, the most common adverse effects included nausea, dizziness, and insomnia.[2]

Public Health Advisory: The FDA has issued a public health advisory regarding the misuse of **Spiriva** (tiotropium) and **Foradil** (formoterol) capsules. Both capsules are designed to be used with their respective inhalation devices, however there have been many reports of patients *swallowing* the capsules instead. While few patients experienced adverse effects from this error, swallowing the capsules has no beneficial effects on the respiratory problems for which they are prescribed. It is vital that pharmacists instruct their patients on the proper use of these products during the counseling session mandated by state law (see **Law Review** on page 2 of this issue). This advisory highlights another case where patient counseling by pharmacists can go a long way toward reducing medication errors and increasing patient compliance.

FDA Reveals Mystery Contaminant in Recalled Heparin: Chondroitin



Heparin structure



Chondroitin structure

The Food and Drug Administration has announced the result of its investigation of heparin products linked to numerous allergic reactions and at least 19 deaths in the United States. The previously unidentified contaminant, found in batches of the product sold by Baxter Healthcare, has been identified as a modified form of **chondroitin sulfate**, a popular supplement used in many over-the-counter products for arthritis (usually in combination with glucosamine). The chondroitin was altered to an oversulfated form which closely resembles the heparin molecule[3] (see structures at left). The lower cost of the contaminant, compared to heparin, has lead to speculation that it was intentionally substituted by manufacturers in China. In a related development, another heparin producer, B. Braun Medical, Inc., has recalled 23 lots of heparin in 5% dextrose and 0.9% sodium chloride due to the discovery of the contaminant by its supplier, Scientific Protein Laboratories (SPL). SPL is also the supplier to Baxter Healthcare, which has already recalled most of its heparin products, as reported in last month's ***PRN***.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Tamper-Resistant Prescription Law in Effect April 1, 2008

The first phase of the new federal tamper-resistant prescription pad law (TRPP) becomes effective on April 1, 2008. The TRPP law mandates that all *written* prescriptions for Medicaid recipients contain tamper-resistant characteristics. By April 1, prescriptions must contain at least one such feature. Effective October, 1, 2008, all prescriptions must contain all three of the federal characteristics, which are:

One or more features designed to prevent unauthorized copying

One or more features designed to prevent erasure or modification

One or more features designed to prevent use of counterfeit forms, such as heat-sensitive ink

This law also applies to fiscal orders for non-prescription drugs and insulin. The official New York State prescription form (ONYSRx) now in use meets all three federal requirements. For prescriptions NOT written on the ONYSRx, the Department of Health has assigned override codes to be used when billing Medicaid. Currently, these codes consist of the following:

HHHHHHHH– for prescriptions written PRIOR to Feb. 25, 2008 by exempt facilities

ZZZZZZZZ– for out-of-state prescriptions

EEEEEEEE– for electronic prescriptions

99999999– for oral prescriptions

NNNNNNNN– for patient-specific orders to a vendor pharmacy for carve-out drugs for nursing home patients

SSSSSSSS– for supply fiscal orders not written on a serialized prescription form

CCCCCCCC– for compound prescriptions using separate NDCs. Use the serial number on the prescription for the first ingredient, use CCCCCCCC for all additional ingredients. When billing for a compound containing multiple controlled substances, use the serial number on the prescription for the controlled substance with the greatest quantity.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Counseling: A Key to Medication Safety

The act of counseling patients about their medications is one of the most crucial and fundamental parts of the pharmacist's duties. Decreased medication errors and increased patient compliance are two examples of the many benefits counseling affords. The Executive Director of the National Association of Boards of Pharmacy, Carmen Catizone, was recently quoted as estimating that patient counseling could catch and prevent 80 percent of the errors that now occur.[4] And a study conducted in 2006, reported in the British Medical Journal, found that pharmacist's counseling of patients (in this case by telephone) lead to improved compliance and was associated with a 41% reduction in the risk of death.[5] These facts argue powerfully for the need for pharmacy organizations, large and small, to adopt workplace strategies that allow pharmacists the time and opportunity to properly counsel their patients.

Regulations

The regulations regarding patient counseling in pharmacy can be found in Title 8 of the New York Codes, Rules, and Regulations (NYCRR), under the Regulations of the Commissioner, Part 63.6 (b)(8). The key elements of these regulations are as follows:

Patient counseling can only be performed by a pharmacist or a registered pharmacy intern

Patient counseling MUST be performed in the following circumstances:

- **When dispensing a medication to a NEW PATIENT of the pharmacy**
- **When dispensing a NEW MEDICATION to an existing patient**
- **When dispensing a prescription previously filled by an existing patient where the DOSE, STRENGTH, DIRECTIONS FOR USE, or ROUTE OF ADMINISTRATION has changed**

For all other situations (patient refilling a prescription or filling a prescription for a medication previously received), an OFFER TO COUNSEL must be made. The offer to counsel may be made by any member of the pharmacy staff, including pharmacy interns, technicians, and clerks. If the patient accepts the offer, a pharmacist or pharmacy intern must be available to provide counseling

If a patient REFUSES COUNSELING, the prescription may still be dispensed as long as the refusal is documented

If a prescription is to be delivered to a patient, a WRITTEN OFFER to counsel must be included with the prescription which provides a phone number at which a pharmacist or pharmacy intern may be readily reached

Counseling Points

When counseling a patient, a pharmacist or pharmacy intern may use his or her professional judgment in choosing what points to discuss. Counseling must be done in a confidential manner, and may include:

Name, description, and use of medication	**Techniques for self-monitoring drug therapy**
Dosage form, route, and duration of therapy	**Proper storage**
Special directions for preparation and use	**Refill information**
Common adverse effects and interactions	**What to do in case of a missed dose**

Rx for Allergy Season

Seasonal allergic rhinitis. Also known as hay fever, seasonal allergic rhinitis affects an estimated 36 million Americans and is responsible for over 14 million physician office visits annually (statistics from the American Academy of Allergy, Asthma, and Immunology at *www.aaaai.org*). The season, which generally runs from spring to autumn, has in recent years begun earlier and lasted longer. Many believe this phenomenon is a result of global warming. In any case, pharmacists can expect to be visited by allergy sufferers soon and often. The mainstays of prescription therapy of allergic rhinitis are second generation antihistamines and steroid nasal sprays. The following chart details the most commonly prescribed agents:

Oral Agents

Product (active)	Type	Pediatric Dose	Adult Dose	Counseling Points
Allegra (fexofenadine 30, 60, 180 mg tabs, 30 mg ODT, 6 mg/ml susp)	2nd Gen Antihistamine	6 mo-2 yo: 15 mg BID* 2-11 yo: 30 mg BID	180 mg QD *or* 60 mg BID	Do not take with antacids or fruit juice
Allegra-D 12 Hour (fexofenadine 60 mg, pseudoephedrine 120 mg tab)	A/D Combo		1 tablet BID	Take on empty stomach Do not crush or chew
Allegra-D 24 Hour (fexofenadine 180 mg, pseudoephedrine 240 mg tab)	A/D Combo		1 tablet QD	Take on empty stomach Do not crush or chew
Clarinex (desloratadine 2.5 mg, 5 mg RediTabs, 5 mg tabs, 0.5 mg/mL syrup)	2nd Gen Antihistamine	6-11 mo: 1 mg QD 1-5 yo: 1.25 mg QD 6-11 yo: 2.5 mg QD	5 mg QD	Take with or without food
Clarinex-D 12 Hour (desloratadine 2.5 mg, pseudoephedrine 120 mg tab)	A/D Combo		1 tablet BID	Do not crush or chew
Clarinex-D 24 Hour (desloratadine 5 mg, pseudoephedrine 240 mg tab)	A/D Combo		1 tablet QD	Do not crush or chew
Semprex-D (acrivastine 8 mg, pseudoephedrine 60 mg tabs)	A/D Combo		1 tablet q4-6h prn (Max: 4 tabs per day)	May cause drowsiness
Xyzal (levocetirizine 5 mg tab)	2nd Gen Antihistamine	6-11 yo: 1/2 tablet qPM	1 tablet qPM	May cause drowsiness

Nasal Sprays

Product (active)	Type	Pediatric Dose	Adult Dose	Counseling Points
Astelin (azelastine 137 mcg/spray)	Antihistamine	5-11 yo: 1 spray in each nostril BID	1 to 2 sprays in each nostril BID	May cause drowsiness
Atrovent Nasal (ipratropium 0.03%)**	Anticholinergic	≥6 yo: 2 sprays in each nostril 2 to 3 times a day	2 sprays in each nostril 2 to 3 times a day	May cause nasal dryness
Beconase AQ (beclomethasone 42 mcg/spray)	Steroid	6-12 yo: 1 to 2 sprays in each nostril BID	1 to 2 sprays in each nostril BID	Shake well before use
Flonase (fluticasone propionate 50 mcg/spray)	Steroid	4-12 yo: 1 to 2 sprays in each nostril QD	2 sprays in each nostril QD	Shake gently before use
Nasacort AQ (triamcinolone 55 mcg/spray)	Steroid	6-12 yo: 1 to 2 sprays in each nostril QD	1 to 2 sprays in each nostril QD	Shake before use
Nasarel (flunisolide 29 mcg/spray)	Steroid	6-14 yo: 2 sprays in each nostril BID *or* 1 spray TID	2 sprays in each nostril 2 to 3 times a day	Does not need shaking
Nasonex (mometasone 50 mcg/spray)	Steroid	2-12 yo: 1 spray in each nostril QD	2 sprays in each nostril QD	Shake well before use
Rhinocort Aqua (budesonide 32 mcg/spray)	Steroid	6-12 yo: 1 to 2 sprays in each nostril QD	1 to 4 sprays in each nostril QD	Shake gently before use
Veramyst (fluticasone furoate 27.5 mcg/spray)	Steroid	2-11 yo: 1 spray in each nostril QD	2 sprays in each nostril QD	Shake well before use

ODT= Orally Disintegrating Tablet Gen= Generation A/D= Antihistamine/Decongestant
* This dose is for chronic idiopathic urticaria ** Atrovent nasal 0.06% is indicated for treatment of the common cold

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Suite C-22
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Phone & Fax (718) 263-4632

Founder and Editor:
James Murphy, RPh

Associate Editor:
Margaret Irving, PharmD

Contributors:
Loriann Irving, PharmD
Lilian Bejarano, RPh

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PRN Publishing
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OFF-LABEL USE: METFORMIN

Editor's Note: This month we introduce a new column, Off–Label Use, *which will be part of a rotation of several different features to appear in this section, including* Natural Products. *PRN does not in any way endorse any off-label uses printed here; they are offered for informational purposes only— always use professional judgment in clinical practice.*

Metformin is indicated for the management of Type 2 Diabetes Mellitus. Off-label uses include:

Polycystic ovary syndrome (PCOS): PCOS is a condition marked by mild obesity, menstrual disturbances, and increased androgen levels. Metformin has been used in PCOS at a dose of 500 mg TID. Metformin appears to reduce excess androgens by lowering insulin levels.

HIV lipodystrophy syndrome: This syndrome, which occurs in patients treated with antiretrovirals (particularly protease inhibitors), is characterized by fat redistribution, insulin resistance, and hyperinsulinemia. Metformin has been used at a dose of 500 mg BID.

Gestational Diabetes: As an alternative to insulin in gestational diabetes, Metformin has been used in some cases at a dose of 500 mg BID.

Obesity: Metformin has been used for obesity in both adults and adolescents, as well as for antipsychotic-induced weight gain. A wide range of doses have been utilized.

DID YOU KNOW?

DID YOU KNOW how seasonal allergic rhinitis originally came to be known as "hay fever"? Coined in the early 1800's, the term referred to a constellation of symptoms which appeared each year around the time of haying season. In addition to hay pollen, a number of other suspected culprits lead to competing names for the disease, which included "rose cold," "peach cold," "June cold," "Summer catarrh," and "Autumnal catarrh." By the 1880's, evidence was mounting that ragweed pollen was the most common cause of the condition,[6] but by then the name had taken hold, and is still in common use today.

PHARMACY FUN

It is said that April showers bring May flowers, and, it being April, we have a flowery quiz for you to solve. For each of the plants, flowers, or trees listed below, name the drug which is, or at one time was, produced therefrom. The first reader to email the correct answers to *puzzle@prnnewsletter.com* wins a custom-printed P.R.N. binder.

1. Purple foxglove
2. French lilac
3. Rauwolfia serpentina
4. Deadly nightshade
5. Chincona ledgeriana
6. Papaver somniferum
7. Ephedra sinica
8. Autumn crocus

Answers to last month's PHARMACY FUN:

1. Insulin 2. Esmolol 3. Botulinum 4. Ramelteon 5. Gemifloxacin 6. Glucagon 7. Ramipril 8. Hydroquinone 9. Nortriptyline 10. Omeprazole 11. Aspirin

Hidden Phrase: ERIN GO BRAGH

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5. Jennifer Y F Wu, et al. Effectiveness of telephone counseling by a pharmacist in reducing mortality in patients receiving polypharmacy: randomized controlled trial. *BMJ* 2006;333:522.
6. "Hay Fever and Its Cure," *New York Times*, September 14, 1884.