P.R.N.

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What's Inside…

FDA NEWS

.Avandia Label Updated

The FDA has announced that the prescription labeling for **Avandia** (rosiglitazone) has now been revised. The new label will reflect the restrictions on the prescribing and use of Avandia, which the agency mandated in September, 2010 in response to evidence of increased cardiovascular risk in those taking the antidiabetic drug. In addition to describing the risk, the new label states that Avandia should only be used:

- **In patients already being treated with this medication**
- **In patients whose blood sugar cannot be controlled with other medications and who, after consulting with their physician, do not wish to use Actos**

A Risk Evaluation and Management Strategy (REMS), which will further restrict the availability of Avandia, is due to be completed by Spring, 2011 and implemented within 6 months thereafter. Until that time, Avandia and Avandia-containing combination products may still be prescribed and dispensed as directed on the revised drug label.

.....NEW DRUGS.....NEW DRUGS.....NEW DRUGS.....

KOMBIGLYZE XR (Saxagliptin and Metformin).
Category: Antidiabetic (DPP-IV and Biguanide combination agent).
Initial Dose: Individualize based on patient's current regimen. Take once daily with the evening meal
MDD: 5 mg Saxagliptin/ 2000 mg Metformin.

Bristol-Myers Squibb and AstraZeneca have received approval to market Kombiglyze XR, a combination of Onglyza and time-released metformin, for the treatment of type 2 diabetes. Kombiglyze XR is not intended for treatment of type 1 diabetes or diabetic ketoacidosis, and has not been studied in combination with insulin. Kombiglyze XR is contraindicated in renal failure, and should be temporarily discontinued in patients undergoing radiologic studies using iodinated contrast materials. Limit the saxagliptin dose to 2.5 mg daily for patients taking strong CYP3A4/5 inhibitors, such as ketoconazole.

LATUDA (Lurasidone HCl).
Category: Antipsychotic (Atypical).
Initial Dose: 40 mg once daily. Take with food.
MDD: 80 mg.

Sunovion Pharmaceuticals is marketing a new atypical antipsychotic call Latuda. In clinical trials, Latuda was less likely to cause weight gain and dyslipidemia than some older atypical antipsychotics. Latuda is not recommended to be used in combination with strong CYP3A4 inhibitors (e.g., ketoconazole) or inducers (e.g., rifampin). The most common adverse effects seen in clinical trials included somnolence, akathisia, nausea, parkinsonism, and agitation. Due to increased mortality in elderly patients, antipsychotics are not approved for the treatment of dementia-related psychosis.

VIIBRYD (Vilazodone HCl).
Category: Antidepressant (SSRI and partial agonist at 5-HT_{1A} receptor).
Initial Dose: 10 mg QD for 7days, then 20 mg QD for 7 days, then 40 mg QD. Take with food.
MDD: 40 mg.

PGxHealth has announced the approval of their new antidepressant, Viibryd, an SSRI and partial 5-HT_{1A} receptor agonist. In clinical trials, Viibryd exhibited lower rates of sexual adverse effects than are typically seen with SSRIs. Do not use Viibryd concomitantly with Monoamine Oxidase Inhibitors (MAOI) or within 14 days of stopping or starting an MAOI. The dose of Viibryd should be reduced to 20 mg daily when used with a strong inhibitor of CYP3A4. As with all antidepressants, Viibryd will carry a **black box warning** about increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants.

BEYAZ (Drospirenone, ethinyl estradiol, levomefolate calcium).
Category: Oral contraceptive.
Initial Dose: One tablet by mouth daily at the same time each day.
MDD: One tablet daily.

Bayer has introduced a new oral contraceptive called Beyaz, which is essentially a new formulation of **Yaz**, the sole difference being the addition of a folate (levomefolate calcium). This new ingredient extends the FDA-approved indications to four, the most for any oral contraceptive on the market. Beyaz is approved for use by women to:

1. **Prevent pregnancy**
2. **Treat symptoms of premenstrual dysphoric disorder**
3. **Treat moderate acne**
4. **Raise folate levels in women who choose to use oral contraceptives**

FDA to Limit Amount of Acetaminophen in Prescription Products

The U.S. Food and Drug Administration (FDA) has announced its intention to limit the amount of acetaminophen in prescription drug products to no more than 325 mg per tablet or capsule. This action is being taken in response to continued reports of acetaminophen-related liver failure. Nearly half of all such cases, many of which result in liver transplantation or death, can be traced to overdoses from prescription combination products containing acetaminophen. A number of popular prescription products will require reformulation, including all three strengths of **Vicodin** (regular, ES, and HP) and two versions of **Percocet** (7.5/500 and 10/650). The change will not be immediate, however; manufacturers have until January, 2014 to comply with the new guidelines.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

New Diabetic Supply Restrictions

Effective March 1, 2011, the New York State Medicaid Program will limit coverage of blood glucose monitors and test strips to include only those products manufactured by **Abbott**, **Bayer**, and **LifeScan**. The change was announced as an update to the *Preferred Diabetic Supply Program*, which was initiated in October, 2009.

Preferred Meters and Strips

- **Ascensia Breeze**
- **Ascensia Contour**
- **Freestyle Lite**
- **Freestyle Freedom Lite**
- **One Touch Ultra**
- **One Touch Ultramini**
- **One Touch Ultra Smart**
- **Precision Xtra**

Non-Preferred Meters and Strips

- **Accu-Chek Active**
- **Accu-Chek Aviva**
- **Accu-Chek Compact**
- **TrueTrack**

Non-preferred meters will not be covered without prior approval beginning on February 1, 2011. Non-preferred strips will continue to be covered until March 1, 2011. Patients currently using a non-preferred meter will need a new fiscal order to obtain preferred monitors and strips. To obtain prior approval for non-preferred products, documentation of medical necessity will be required and, if approved, non-preferred products must be billed using HCPCS codes on a DME claim form. Pharmacists may access the current Preferred Supply List at: ***https://newyork.fhsc.com*** by clicking on Preferred Diabetic Supply Program under the "Providers" tab. Pricing information is available at ***www.emedny.org***.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

New York Prescription Saver Card Program

The New York State Department of Health has established a State-sponsored drug discount card program. The program, known as the New York Prescription Saver (NYPS), was initiated on April 1, 2009. To date, approximately 7,000 New Yorkers have enrolled. The NYPS was designed to help uninsured, lower income, disabled, and near-elderly individuals, who are not eligible for Medicaid or EPIC, afford their prescription medications. The program depends upon discounts provided by participating pharmacies, as well as manufacturers, which make it possible for enrollees to obtain lower prices for covered prescriptions. The Department of Health has provided answers to some of the most commonly asked questions about the program:

Who is eligible for the NYPS?

The program is open to New York State residents who are 50 to 64 years of age, or Social Security disabled, ***and*** have an annual household income of up to $35,000 for singles and up to $50,000 for married couples ***and*** are NOT receiving Medicaid benefits.

Is there an enrollment or application fee?

No, there is no fee to enroll in NYPS.

What drugs are covered? Are diabetic supplies included?

The NYPS program covers the same drugs that are covered by EPIC. This includes prescription drugs plus insulin and insulin syringes and needles. Test strips and glucose monitors are not covered.

Can the NYPS card be used with other drug coverage or discount cards?

No. The member can have other drug discount cards or coverage along with the NYPS card, but only one card can be used for each purchase.

If the card member has Medicare Part D or other insurance, can the NYPS card be used for drugs not covered by the plan? How about for the deductible and "doughnut hole"?

If the member is under age 65 and has Medicare Part D (e.g., disabled persons), they may use the NYPS card **instead** of their Part D plan, but they cannot use the discount card **and** another insurance card for the same purchase.

If the member has Medicare Part D as is in their deductible or "doughnut hole," they can use the NYPS card instead of their Part D card to get the discount on their purchases. According to Medicare, they can get credit for these purchases toward their deductible or out-of-pocket limit by sending in the paper receipt to their Part D plan; the pharmacy cannot bill the plan directly.

How to apply for the NYPS card:

The NYPS application is available online at:
https://nyprescriptionsaver.fhsc.com

The application can be filled out and submitted online, or printed out and mailed to NYPS, P.O. Box 12069, Albany New York 12212-2069. In addition, applications can be taken over the phone by calling 1-800-788-6917. Pharmacists are encouraged to assist patients in filling out the application if they need help.

Is there a list of drug prices available?

Yes. The current list of the top 1,500 most commonly prescribed drugs is available at ***https://nyprescriptionsaver.fhsc.com*** by clicking on the "Drug Prices" tab. Drugs can be searched for alphabetically or by therapeutic category. A list of participating providers is also available on the NYPS website.

Feature Article..

INSULIN CLASSIFICATION AND STORAGE REQUIREMENTS

Recent advances in insulin formulations and delivery devices have made it imperative that pharmacists keep up with the latest specifications for the storage and stability of each individual product. Below is our up-to-date chart on the classification and storage requirements of commercially available insulin products.

Rapid Acting Insulins

Brand Name	Onset of Action	Duration of Action	Storage/Stability of In-Use (Opened) Vials	Storage/Stability of In-Use (Opened) Pens
Apidra (Glulisine)	12 to 30 minutes	3 to 5 hours	Refrigerate or Room Temp: Use within **28 days**	Do Not Refrigerate: Use within **28 days**
Humalog (Lispro)	15 to 30 minutes	3 to 5 hours	Refrigerate or Room Temp: Use within **28 days**	Do Not Refrigerate: Use within **28 days**
Novolog (Aspart)	12 to 20 minutes	3 to 5 hours	Refrigerate or Room Temp: Use within **28 days**	Do Not Refrigerate: Use within **28 days**

Short Acting Insulins

Brand Name	Onset of Action	Duration of Action	Storage/Stability of In-Use (Opened) Vials	Storage/Stability of In-Use (Opened) Pens
Humulin R	30 minutes	4 to 12 hours	Refrigerate or Room Temp: Use within **28 days**	Not Applicable
Novolin R	30 minutes	4 to 12 hours	Refrigerate or Room Temp: Use within **42 days**	Not Applicable

Intermediate Acting Insulins

Brand Name	Onset of Action	Duration of Action	Storage/Stability of In-Use (Opened) Vials	Storage/Stability of In-Use (Opened) Pens
Humulin N	1 to 2 hours	14 to 24 hours	Refrigerate or Room Temp: Use within **28 days**	Do Not Refrigerate: Use within **14 days**
Novolin N	1 to 2 hours	14 to 24 hours	Refrigerate or Room Temp: Use within **42 days**	Not Applicable

Long Acting Insulins

Brand Name	Onset of Action	Duration of Action	Storage/Stability of In-Use (Opened) Vials	Storage/Stability of In-Use (Opened) Pens
Lantus (Glargine)	3 to 4 hours	24 hours	Refrigerate or Room Temp: Use within **28 days**	Do Not Refrigerate: Use within **28 days**
Levemir (Detemir)	3 to 4 hours	6 to 23 hours (Dose-dependent)	Refrigerate or Room Temp: Use within **42 days**	Do Not Refrigerate: Use within **42 days**

Combination Insulins

Brand Name	Onset of Action	Duration of Action	Storage/Stability of In-Use (Opened) Vials	Storage/Stability of In-Use (Opened) Pens
Humalog Mix	15 to 30 minutes	14 to 24 hours	Refrigerate or Room Temp: Use within **28 days**	Do Not Refrigerate: Use within **10 days**
Humulin 70/30	30 minutes	18 to 24 hours	Refrigerate or Room Temp: Use within **28 days**	Do Not Refrigerate: Use within **10 days**
Novolin 70/30	30 minutes	18 to 24 hours	Refrigerate or Room Temp: Use within **42 days**	Not Applicable
Novolog Mix	12 to 20 minutes	18 to 24 hours	Refrigerate or Room Temp: Use within **28 days**	Do Not Refrigerate: Use within **14 days**

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ASK PRN...

The label on the new anticoagulant drug Pradaxa states that "once opened, the product must be used within 30 days." The manufacturer also states that Pradaxa must be stored in the original container. Why does this product have such an unusual expiration protocol? How can a pharmacist fill a prescription that calls for less than a 30-day supply (e.g., a prescriber calls in a 1 week supply to hold the patient over until their next visit)?

According to the manufacturer, Boehringer Ingelheim, Pradaxa capsules are filled with small pellets which are sensitive to humidity. The desiccant, which helps maintain the product's stability, is actually located in the bottle's cap, hence Pradaxa must be stored in the original manufacturer's container. Even when properly stored, the capsules maintain full potency for only 30 days after the bottle has been opened. This presents several unique challenges for pharmacists and their patients. In the case of any prescription for less than a 30-day supply, the pharmacist must order and dispense Pradaxa in unit dose blister packs, which are available in packages containing 10 blister packs of 6 capsules each (*NDC # 00597-0135-60* for the 150 mg strength). For prescription calling for 60 capsules (a 1 month supply), the bottle may be dispensed, but pharmacists should alert their patients not to open the bottle until they are ready to start taking the medication, mark the date of opening on the bottle, and discard any capsules remaining after 30 days. This is particularly important if a patient refills their prescription a few days early; in that case it is crucial that the patient knows not to open the new bottle until they have completely finished the previously dispensed supply.

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 both **Listerine®**, the oral antiseptic, and the genus of bacteria known as *Listeria*, were both named in honor of the same man? Joseph Lister, a British surgeon working in Glasgow in the late 1800's, pioneered the use of antiseptics in surgery, greatly reducing the mortality rate. Lister used phenol, then known as carbolic acid, to clean surgical instruments and wounds, and insisted that surgeons working under him wash their hands before and after every procedure. Lister's methods were not widely accepted at first, but eventually became the standard of practice.

PHARMACY FUN

It's anagram time again - cold and flu season edition! Unscramble the following sentences to find the names of popular cold and flu medications (they may be brand or generic names, prescription or OTC). The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. Flu it am!
2. I am flu end
3. Faded us
4. Half true
5. Mania at end
6. Real zen

Answers to last issue's **PHARMACY FUN**:
1. Questran 2. Welchol 3. Ezetimibe 4. Rosuvastatin 5. Triglyceride 6. Yeast
Hidden word: QWERTY (as in keyboard!)

A Note From The Editor...

With this issue, we are announcing some changes to ***PRN***. The newsletter will now be published on a bi-monthly basis, 6 issues per year. In addition, each edition will now be identified by number, rather than in the previous volume/issue format. We believe this will make it easier to cross reference and access articles in previous issues. We look forward to continuing to serve the retail pharmacy community and we thank you for your support.