# P.R.N.

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**What's Inside…**



## FDA NEWS

### FDA Warns of Arrhythmia with High Dose Celexa

The FDA has issue a Drug Safety Communication regarding abnormal heart rhythms associated with the use of high doses of Celexa (citalopram). The agency has determined that Celexa causes a dose-dependent prolongation of the QT interval, which can lead to potentially fatal arrhythmias (including Torsade de Pointes). The FDA has published the following guidelines for healthcare professionals:

- **Celexa should not be prescribed at doses greater than 40 mg per day (*the previous MDD was 60 mg)***
- **Celexa should not be used in patients with congenital long QT syndrome**
- **20 mg per day is the <u>maximum</u> dose recommended for patients with hepatic impairment, who are greater than 60 years of age, who are CYP 2C19 poor metabolizers, or who are taking Tagamet (cimetidine), because these factors increase the risk of arrhythmia**

## .....NEW DRUGS.....NEW DRUGS.....NEW DRUGS.....

**BRILINTA** (Ticagrelor).
**Category:** Platelet Inhibitor.
**Initial dose:** 180 mg loading dose, followed by 90 mg twice a day, taken with or without food.
**MDD:** 180 mg.

AstraZeneca has received FDA approval to market Brilinta, a $P2Y_{12}$ platelet inhibitor indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS). In clinical trials, Brilinta was more effective than Plavix in preventing heart attacks and death. Brilinta was studied in combination with low-dose aspirin (75 to 100 mg), and the effects of Brilinta are decreased in patients taking more than 100 mg of aspirin daily. The most common adverse reactions seen were dyspnea (14%) and bleeding (12%). Dyspnea was usually mild to moderate and often resolved with continued use. As with other platelet inhibitors, Brilinta contains a **black box warning** regarding the risk of bleeding, but includes this additional statement about aspirin:

- **Maintenance doses of aspirin above 100 mg reduce the effectiveness of Brilinta and should be avoided. After any initial dose, use with aspirin 75 to 100 mg per day**

Brilinta is primarily metabolized by CYP 3A4; concomitant use of strong inhibitors or inducers should be avoided. Digoxin levels should be monitored with initiation or any change in Brilinta therapy. Patients taking Brilinta should not exceed 40 mg daily of either simvastatin or lovastatin.

**COMPLERA** (Emtricitabine/Rilpivirin/Tenofovir).
**Category:** Antiretroviral Combination for HIV.
**Initial dose:** One tablet taken once daily with a meal.
**MDD:** One tablet.

The FDA has approved Complera, a single-tablet complete regimen for the treatment of HIV in treatment-naïve adults. Complera, marketed by Gilead Sciences, Inc., contains 2 nucleoside reverse transcriptase inhibitors (emtricitabine and tenofovir) and 1 non-nucleoside reverse transcriptase inhibitor (rilpivirin). Complera is the second complete antiretroviral combination approved for treatment-naïve patients (**Atripla** was the first), and, as such, should not be administered with other antiretroviral mediations for the treatment of HIV. The manufacturer recommends that Complera always be dispensed and stored in the original container.

**ARCAPTA NEOHALER** (Indacaterol Inhalation).
**Category:** Long-Acting Beta$_2$ Agonist (LABA).
**Initial dose:** 75 mcg inhaled once daily.
**MDD:** 75 mcg.

Novartis Pharmaceuticals will introduce Arcapta Neohaler in early 2012. Arcapta is a long-acting beta$_2$ agonist (LABA) indicated for the long term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including bronchitis and emphysema. Arcapta is not indicated for asthma or for acute exacerbations of COPD. Arcapta comes in blister-packed capsules which are punctured for inhalation through the supplied Neohaler device.

## Infant's Acetaminophen Concentration Changed to Reduce Errors

The makers of infants' acetaminophen will change the concentration of their products from **80 mg per 0.8 mL** to **160 mg per 5 mL**, to match the concentration of the children's syrup and suspension products. This change, based on the 2009 recommendation of an FDA Advisory Committee, will be industry-wide and will lead to a single concentration of 160mg/5mL for all OTC pediatric single-ingredient liquid acetaminophen products. The FDA recommendation was based on numerous reports of dosing errors due to confusion between the two available concentrations of pediatric acetaminophen. Pharmacists should be aware that, during the transition, some products containing the old concentration of 80 mg/0.8mL will still be available. When counseling parents on OTC purchases or dispensing liquid acetaminophen by prescription on state-sponsored programs, always ensure that the dose is appropriate for the patient's age and weight based on the particular concentration being purchased or dispensed.

# MEDICAID UPDATE SPECIAL EDITION: FORMULARY CHANGES

*Information Regarding the New York State Medicaid Program*

Effective August 25, 2011, the New York State Medicaid Program will institute several major changes in the Preferred Drug Program. In addition to adding 9 new categories of non-preferred drugs, the Department of Health has also, for the first time, made the changes retroactive. The following statement appeared on the Medicaid Prior Authorization website (***www.newyork.fhsc.com***):

**Effective August 25, 2011, once a prior authorization (PA) requirement is implemented for a drug, all new prescriptions and any refills remaining on existing prescriptions will require prior authorization.**

**This change means that PA requirements will no longer be dependent on the date a prescription is written. New prescriptions and refills on existing prescriptions will require PA even if the prescription was written before the date the drug was determined to require PA.**

Below we have listed the preferred and non-preferred drugs in several of the newly designated categories.

| **Anti-Fungals - Topical: Preferred** | |
|---|---|
| clotrimazole OTC | Nyamyc |
| miconazole OTC | Nystop |
| nystatin (cream, oint.) | Pedi-Dri |
| nystatin powder | terbinafine OTC |
| nystatin/triamcinolone | tolnaftate OTC |

| **Anti-Fungals - Topical: Non-Preferred** | |
|---|---|
| clotrimazole Rx | Lamisil AT |
| clotrimazole/betamethasone | Loprox |
| ciclopirox | Lotrisone |
| econazole | Mentax |
| Ertaczo | Naftin |
| Exelderm | Oxistat |
| Extina | Tinactin |
| ketoconazole | Vusion |

| **Steroids, Topical - Low Potency: Preferred** |
|---|
| hydrocortisone acetate OTC |
| hydrocortisone acetate Rx |
| hydrocortisone/aloe vera |

| **Steroids, Topical - Low Potency: Non-Preferred** | |
|---|---|
| alclometasone | Desonate |
| Aclovate | Nucort |
| Derma-Smoothe/FS | Texacort |
| desonide | Verdeso |

| **Steroids, Topical - Medium Potency: Preferred** |
|---|
| fluocinolone |
| hydrocortisone valerate |

| **Steroids, Topical - Medium Potency: Non-Preferred** | |
|---|---|
| Cloderm | hydrocortisone butyrate |
| Cordran | Luxiq |
| Cutivate | mometasone furoate |
| Dermatop | Pandel |
| Elocon | prednicarbate |
| fluticasone propionate | |

| **Steroids, Topical - High Potency: Preferred** | |
|---|---|
| amcinonide | fluocinonide emollient |
| fluocinonide | triamcinolone acetonide |
| fluocinonide-E | |

| **Steroids, Topical - High Potency: Non-Preferred** | |
|---|---|
| Apexicon, Apexicon-E | Diprolene, Diprolene AF |
| Beta-Val | Halog |
| betamethasone dip. | Kenalog |
| betamethasone dip. aug. | Topicort |
| betamethasone valerate | Topicort LP |
| desoximetasone | Trianex |

| **Steroids, Topical - Very High Potency: Preferred** |
|---|
| clobetasol |
| halobetasol |

| **Steroids, Topical - Very High Potency: Non-Preferred** | |
|---|---|
| Clobex | Temovate |
| Cormax | Temovate-E |
| Olux | Ultravate |
| Olux-E | |

*Feature Article..*

# PREPARING FOR THE 2011/2012 FLU SEASON

**Flu Season** is almost upon us, and there have been a few changes in the prevention and treatment of seasonal influenza that pharmacists should be familiar with. Below we review the latest recommendations from the Centers for Disease Control and Prevention (CDC).

## The Vaccine

The 2011/2012 influenza vaccine is a trivalent vaccine containing the same 3 components as the 2010/2011 vaccine:

- **A/California/7/2009(H1N1)**
- **A/Perth/16/2009(H3N2)**
- **B/Brisbane/60/2008**

The vaccine is available in a trivalent inactivated form for IM injection (TIV- *Afluria, Fluarix, FluLaval, Fluvirin, Fluzine*), and a live attenuated form for intranasal use (LAIV- *FluMist*). Additionally, *Fluzone* is available in an intradermal microinjection form and in a high dose IM version for patients ≥65.

## Who Should Get Vaccinated?

The CDC is continuing its recommendation for "universal" flu vaccination, first issued in February, 2010. For certain people, however, vaccination is especially important because they are at high risk of developing complications. These include:

- **Pregnant women**
- **Children younger than 5**
- **People 50 years of age and older**
- **People who live in nursing homes**
- **People who live with or care for those at high risk, such as health care workers, household contacts and out of home caregivers of children less than 6 months of age**

## Dosage, Administration, and Storage (TIV)

The adult dose for TIV is **0.5 mL** given intramuscularly in the deltoid muscle. Vials and prefilled syringes should be shaken before use and a needle of at least **1 inch** should be used to ensure penetration of muscle tissue. The CDC does not recommend the prefilling of syringes by providers, but if it is done, no more than 10 doses should be drawn, and any syringes not used by the end of the day should be discarded. TIV should be refrigerated (2° to 8°C) and temperatures should be read and recorded twice a day. Temperature logs should be kept for at least 3 years.

## Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza

There are four drugs approved for use against seasonal influenza: amantadine, rimantadine, oseltamivir, and zanamivir. Due to resistance, amantadine and rimantadine are no longer recommended for use. The approved uses for oseltamivir and zanamivir are summarized below.

| Antiviral | Active against | FDA approved for treatment | FDA approved for prophylaxis | Not recommended for use in: |
|---|---|---|---|---|
| **Tamiflu** (oseltamivir) | Influenza A and B | 1 year of age and older | 1 year of age and older | None |
| **Relenza** (zanamivir) | Influenza A and B | 7 years of age and older | 5 years of age and older | People with underlying respiratory disease |

## Tamiflu Oral Suspension Has Been Reformulated: Updated Pediatric Dosing Chart

In an effort intended to minimize the risk of dosing errors, Genentech has reformulated Tamiflu for Oral Suspension with a new strength **of 6mg/mL** (the original product had a concentration of 12 mg/mL). There are also new emergency compounding instructions for pharmacists in the event of a shortage of the manufactured product (see this month's ***ASK PRN*** on page 4 for details).

**Pediatric Dosing Chart for Reformulated Tamiflu 6mg/mL Suspension**

| Weight (kilograms) | Weight (pounds) | Treatment Dosing for 5 Days | Prophylaxis Dosing for 10 Days | Volume of Suspension per Dose | Number of Bottles to be Dispensed |
|---|---|---|---|---|---|
| 15 kg or less | 33 lbs or less | 30 mg **BID** | 30 mg **QD** | 5 mL | 1 bottle |
| 16 to 23 kg | 34 to 51 lbs | 45 mg **BID** | 45 mg **QD** | 7.5 mL | 2 bottles |
| 24 to 40 kg | 52 to 88 lbs | 60 mg **BID** | 60 mg **QD** | 10 mL | 2 bottles |
| 41 kg or more | 89 lbs or more | 75 mg **BID** | 75 mg **QD** | 12.5 mL | 3 bottles |

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# ASK PRN...

**Now that Tamiflu for Oral Suspension has been reformulated, has there been any change to the emergency compounding instructions for pharmacists?**

Yes. The original Tamiflu for Oral Suspension, when reconstituted, had a final concentration of 12 mg per mL. Due to shortages during the 2009 flu season, the FDA approved an emergency compounding protocol for pharmacists, to be used only when the commercially manufactured product was unavailable. The final concentration of the compounded product was 15 mg per mL, which led to some confusion and the possibility of dosing errors. In order to avoid this problem, the new compounding instructions yield a product with a concentration identical to the reformulated commercial version: 6 mg per mL. The new emergency compounding instructions for pharmacists as follows: First determine the final volume of the suspension and the number of capsules and amount of water and vehicle to be used according to the chart we have prepared below.

Then follow these steps:

1. **Place the specified amount of water in a prescription bottle (PET or glass)**
2. **Pour the contents of the required number of Tamiflu 75 mg capsules into the bottle**
3. **Gently swirl the suspension for at least 2 minutes to wet the powder**
4. **Slowly add the specified amount of vehicle to the bottle**
5. **Close the bottle and shake well for 30 seconds**
6. **Label the bottle "Shake Well Before Use" and indicate that any unused suspension remaining after completion of therapy must be discarded**
7. **Place the appropriate expiration date on the label: Product is stable for 5 days at room temperature or 35 days when refrigerated at 2° to 8°C (36° to 46°F)**

**New Tamiflu Suspension Emergency Compounding Instructions for Pharmacists**

| Patient's Weight | Dose* | Required Number of 75 | Required Volume of | Required Volume of | Final Volume of |
|---|---|---|---|---|---|
| 15 kg or less | 5 mL (30 mg) | 6 | 5 mL | 69 mL | 75 mL |
| 16-23 kg | 7.5 mL (45 mg) | 8 | 7 mL | 91 mL | 100 mL |
| 24 to 40 kg | 10 mL (60 mg) | 10 | 8 mL | 115 mL | 125 mL |
| 41 kg or more | 12.5 mL (75 mg) | 12 | 10 mL | 137 mL | 150 mL |

* Dose is given twice a day for 5 days for treatment, once a day for 10 days for prophylaxis
** Approved vehicles are: Cherry Syrup (Humco), Ora-Sweet SF (Paddock), and simple syrup

*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.*

## PHARMACY FUN

**It's not every day that you come across a puzzle based on physicians' notoriously bad handwriting, so when we saw this one we just had to steal it! It was created by Michael Wortman and originally appeared on the Puzzler segment of NPR's "Car Talk" program. The question: what is interesting about this sentence?**

"I do not know where family doctors acquired illegibly perplexing handwriting, nevertheless extraordinary pharmaceutical intellectuality counterbalancing indecipherability transcendentalizes intercommunications incomprehensibleness."

**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. Lariam 2. Reyataz 3. Clindamycin

Photograph by James Murphy