P.R.N.

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What's Inside…

FDA NEWS

Change in Tamiflu Dosing

When the FDA authorized the emergency use of **Tamiflu** (oseltamivir) in children less than 1 year of age, the agency released dosing information based on age (see the April, 2009 issue of ***PRN***). That information has now been updated to the preferred weight-based method of determining dose. The recommended treatment dose for infants less than 1 year of age is :

3 mg/kg/dose twice a day for 5 days

The recommended prophylaxis dose for children 3 months to less than 12 months of age is:

3 mg/kg/dose once daily for 10 days

Weight-based dosing is preferred, but if weight is not known prescribers may revert to the previously issued age-based dosing.

The FDA also issued guidance on the compounding of Tamiflu suspension during a shortage of the commercial product. Pharmacies may compound the suspension *in advance* in quantities using no more than 100 capsules at a time (approximately 8 to 16 bottles of 15mg/mL suspension depending on dose).

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

New Antihypertensive Combo: Boehringer Ingelheim Pharmaceuticals has received FDA approval to market **Twynsta**, a combination antihypertensive containing the angiotensin II receptor blocker **Micardis** (telmisartan) and the calcium channel blocker **Norvasc** (amlodipine). Twynsta is indicated for the treatment of hypertension, either alone or with other antihypertensive agents. Twynsta may be used as initial therapy in those patients likely to need multiple antihypertensive agents to reach their blood pressure goals. In clinical trials, the most common adverse effects were peripheral edema, dizziness, and orthostatic hypotension. Twynsta contains a **black box warning** to avoid use in pregnancy. Patients with heart failure should be monitored for worsening of symptoms, since amlodipine may increase the incidence of pulmonary edema in this population. The recommended starting dose of Twynsta is one 40mg/5mg tablet daily. The majority of antihypertensive effect is attained within 2 weeks. Dosage may be increased after at least 2 weeks to a maximum dose of 80mg/10mg once daily. Twynsta will be available in the following strengths: **40mg/5mg**, **40mg/10mg**, **80mg/5mg**, and **80mg/10mg**.

New Topical NSAID: Mallinckrodt Pharmaceuticals will market **Pennsaid** (diclofenac sodium topical solution) for the treatment of symptoms of osteoarthritis of the knee(s). Pennsaid is applied directly to the affected knee, 10 drops at a time, until a total of 40 drops have been applied and the knee is completely covered with solution. Hands should be washed after use.

New FDA Indications: The FDA has recently approved a number of new indications for drugs already on the market. These new indications include:

Crestor (rosuvastatin) is now approved for use in pediatric patients 10 to 17 years of age with heterozygous familial hypercholesterolemia (HeFH) who have failed an adequate trial of diet therapy. The dosage range for pediatric patients is 5 to 20mg/day.

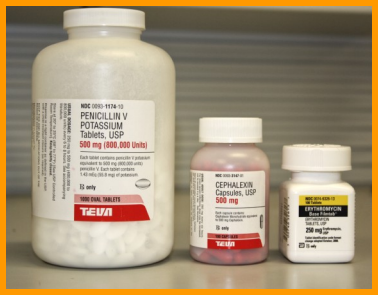
Welchol (colesevelam) has been approved to reduce LDL-C levels in boys and postmenarchal girls 10 to 17 years of age with HeFH as monotherapy or in combination with a statin after failing an adequate trial of diet therapy. Welchol is now also available in a powder for oral suspension in packets containing 1.875 gm or 3.75 gm. The pediatric dose is 3.75 gm once daily or 1.875 gm BID.

Micardis (telmisartan) has been given an additional indication for the reduction of the risk of myocardial infarction, stroke, or death from cardiovascular causes in patients 55 years of age or older at high risk of developing major cardiovascular events who are unable to take ACE inhibitors. The dose for this indication is 80 mg once daily.

Colcrys (colchicine), the only FDA-approved colchicine for the treatment of gout flares, is now also indicated for prophylaxis of gout flares. The prophylactic dose is 0.6 mg once or twice daily in adults and adolescents older than 16 years of age.

CDC Studies Use of Antibiotics During Pregnancy

The Centers for Disease Control and Prevention (CDC) has conducted a study of the association between birth defects and the use of antibiotics during the first trimester of pregnancy. The research consisted of a population-based, multisite, case-control study of women who had pregnancies affected by 1 of more than 30 eligible major birth defects. The data indicate that antibiotic use is common during pregnancy and increases during early pregnancy. The most commonly reported class of antibiotics used during the first trimester were penicillins; erythromycins were the second most commonly used class. The authors' analysis of the data supported the established safety profile of three antibiotic classes: penicillins, erythromycins, and cephalosporins. However, an increased association with a number of birth defects was found among women taking antibiotics from two other classes: sulfonamides and nitrofurantoins. While there are already cautions against the use of these agents, especially at or near term due to the possibility of kernicterus with sulfonamides and hemolytic anemia with nitrofurantoins, this study suggests that additional scrutiny of these two classes of antibiotics is warranted.



MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Elidel and Protopic Added to Clinical Drug Review Program

The topical immunomodulators **Elidel** (pimecrolimus) and **Protopic** (tacrolimus) have been added to the New York State Medicaid Clinical Drug Review Program (CDRP). The CDRP is a prior authorization program intended to ensure that specific drugs are used in a clinically appropriate manner. Drugs included in the CDRP may pose safety issues, public health concerns, or have the potential for fraud and misuse. Both Elidel and Protopic carry **black box warnings** regarding association with rare cases of malignancy, including skin and lymphoma.

Prior Authorization Process

To obtain prior authorization for Elidel or Protopic, the prescriber, or an authorized agent of the prescriber, must call the prior authorization call line at:

1-877-309-9493

This line is available 24 hours a day, 7 days a week. In addition to requesting patient and prescriber information, four questions specific to topical immunomodulators will be asked:

1. **Is the patient diagnosed with atopic dermatitis?**
2. **Did the patient attempt using a topical corticosteroid for 4 weeks?**
3. **Has the patient experienced a treatment failure, a clinically significant adverse reaction, or does the patient have a contraindication to a topical corticosteroid?**
4. **Is the patient immunocompromised? If yes, does the patient have HIV with facial seborrheic dermatitis?**

Once obtained, the prior authorization is valid for the life of the prescription (up to 5 refills are allowed).

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

News from the Annual Pharmacy Law Day Seminar

The Arnold and Marie Schwartz College of Pharmacy held its 27th annual update on pharmacy laws and regulations on November 1, 2009. The College's director of continuing education, Joseph J. Bova, RPh, introduced a program which included such topics as pharmacy litigation, healthcare reform, Medicare Part D, the Office of Professional Discipline, and current issues for the New York State Board of Pharmacy. Here are some of the highlights.

Medicare Part D Updates for 2010

A number of changes in the Medicare Part D program are set to take effect in 2010, including:

- **Part D sponsors must have available on their websites any prior authorization criteria, quantity limit restrictions, and step therapy requirements associated with their plans**
- **Sponsors are required to notify beneficiaries *prospectively* of any transfer of prescriptions to mail-order**
- **The cost threshold for Medication Therapy Management (MTM) has been lowered from $4000 to $3000**
- **Eligible beneficiaries will be targeted for MTM services at least quarterly each year, using an opt-out method of enrollment**
- **There is now a single contractor, Humana, to handle immediate need and retroactive coverage for dual-eligible and low income subsidy beneficiaries who do not have a Part D plan. The bin number for this plan is 610649 and the pcn is 05440000. Instructions for billing are available at: *www.humana.com/pharmacists/resources/li_net.asp***

In addition, effective January 1, 2013, **barbiturates** and **benzodiazepines**, currently excluded, will become covered Part D drugs.

Current Issues for the New York State Board of Pharmacy

Current board of pharmacy member Daniel Molina, RPh, spoke on topics relevant to community pharmacy practice in New York State, which included:

- **Automatic refill programs *require informed consent* (patient must opt-in) and are *not permitted* for Medicaid beneficiaries**
- **"Returns to stock," often a consequence of automatic refill programs, should be used as soon as possible. Under no circumstances may these drugs be dispensed to patients beyond 6 months from the date the drugs were first prepared for dispensing**
- **Bilingual labeling: while a prescription label may contain instructions in a language other than English, the label and the pharmacy records must also contain the required information in English**
- **Expect legislation regarding the licensing and/or regulation of pharmacy technicians within the next 18 to 24 months**
- **Electronic recordkeeping: as reported in this column earlier, section 29.7 of the Regent's Rules has been amended to allow for oral prescriptions to be stored electronically, without producing a hard copy, which shall include the electronic equivalent of a signature or readily identifiable initials of the receiver of the oral prescription. Electronically transmitted prescriptions may also be stored electronically, and the daily record of prescriptions filled and refilled may consist of an electronic record, rather than a printout, which must be signed electronically.**

Feature Article..

REVIEW OF ORAL ANTIDIABETIC DRUGS

November is American Diabetes Month. According to the American Diabetes Association, nearly 24 million Americans are afflicted with diabetes, and another 57 million are at risk for developing the disease. The majority of diabetics (90 to 95%) are categorized as Type 2, the form of the disease which is treated primarily with oral antidiabetic agents. While most diabetic children are classified as Type 1, which requires insulin therapy, in recent years an alarming number of young people have been diagnosed as Type 2 diabetics, possibly as a result of an epidemic of childhood obesity in the United States. These statistics highlight the need for pharmacists to keep informed of the latest developments in the treatment of Type 2 diabetes with oral antidiabetic agents.

I. Sulfonylureas - Long-Acting Insulin Secretagogues*

Drug (brand name, strengths available)	Starting Dose	MDD	Timing With Meals	Adverse Effects
Glimeperide (Amaryl, 1, 2, 4 mg)	1 to 2 mg QD	8 mg	Take with first meal	Hypoglycemia, dizziness
Glipizide (Glucotrol, 5, 10 mg)	5 mg QD	40 mg	30 minutes before first meal	Hypoglycemia, weight gain
Glipizide ER (Glucotrol XL, 2.5, 5, 10 mg)	5 mg QD	20 mg	Take with first meal	Hypoglycemia, weight gain
Glyburide (Diabeta, 1.25, 2.5, 5 mg)	2.5 to 5 mg QD	20 mg	Take with first meal	Hypoglycemia, weight gain

II. Meglitinides - Short-Acting Insulin Secretagogues

Drug (brand name, strengths available)	Starting Dose	MDD	Timing With Meals	Adverse Effects
Repaglinide (Prandin, 0.5, 1, 2 mg)	0.5 to 1 mg TID	16 mg	15-30 minutes before meals	Hypoglycemia, weight gain

III. Phenylalanine Derivatives - Short-Acting Insulin Secretagogues

Drug (brand name, strengths available)	Starting Dose	MDD	Timing With Meals	Adverse Effects
Nateglinide (Starlix, 60, 120 mg)	60 to 120 mg TID	360 mg	1-30 minutes before meals	Hypoglycemia, weight gain

IV. Alpha-Glucosidase Inhibitors

Drug (brand name, strengths available)	Starting Dose	MDD	Timing With Meals	Adverse Effects
Acarbose (Precose, 25, 50, 100 mg)	25 mg TID	300 mg	Take with first bite of meal	Flatulence, diarrhea
Miglitol (Glyset, 25, 50, 100 mg)	25 mg TID	300 mg	Take with first bite of meal	Flatulence, diarrhea

V. Biguanides

Drug (brand name, strengths available)	Starting Dose	MDD	Timing With Meals	Adverse Effects
Metformin (Glucophage, 500, 850, 1000mg)	500 mg BID or 850 mg QD	2.55 gm	Take with food	Diarrhea, nausea, vomiting
Metformin ER (Glucophage XR, 500, 750 mg)	500 mg qPM	2 gm	Take with food	Diarrhea, nausea, vomiting

VI. Thiazolidinediones

Drug (brand name, strengths available)	Starting Dose	MDD	Timing With Meals	Adverse Effects
Pioglitazone (Actos, 15, 30, 45 mg)	15 mg QD	45 mg	Take with or without food	Edema, weight gain
Rosiglitazone (Avandia, 2, 4, 8 mg)	4 mg QD	8 mg	Take with or without food	Edema, weight gain

VII. Dipeptidyl Peptidase IV (DPP-IV) Inhibitors

Drug (brand name, strengths available)	Starting Dose	MDD	Timing With Meals	Adverse Effects
Saxagliptin (Onglyza, 2.5, 5 mg)	2.5 to 5 mg QD	5 mg	Take with or without food	Headache, URI
Sitagliptin (Januvia, 25, 50, 100 mg)	100 mg QD	100 mg	Take with or without food	Headache, URI

Key: MDD = Maximum Daily Dose URI = Upper Respiratory Infection
* Only second generation agents listed (first generation sulfonylureas are no longer in common use)

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ASK PRN...

The regulations regarding oral prescriptions for schedule IV controlled substances state that a pharmacist may dispense a 30-day supply or 100 dosage units, whichever is less. This wording has led to some argument as to the maximum quantity allowed on prescriptions with multiple tablet sigs (e.g., take 2 tablets 3 times a day) and prescriptions for liquid dosage forms. What is the correct approach to this question?

If you consider that a "dosage unit" is equal to the quantity of each dose, whether that dose is 1 or 2 tablets or more (or 5 or 10 ml, etc.), then it's rather easy to calculate what the maximum allowable supply would be for any prescription. In fact, we have come up with a little formula that will answer the question instantly for any given Rx. For any prescription with a sig of QD, BID, or TID, the 30-day supply will always be the maximum quantity allowed. For any Rx with a sig of QID or greater, the maximum quantity allowed will always be 100 dosage units. This is simply because, regardless of the size of the dosage unit, a sig of QID or more will always yield at least 120 dosage units monthly. Here is an example (keep in mind that a "dosage unit" is equal to the number of tablets *per dose*):

Rx #1: Phenobarbital 30 mg 1 tab QID
30-day supply = *120* which is *greater* than 100 dosage units (100 tablets):
Rule: sig ≥ QID give 100 dosage units

Rx #2: Phenobarbital 30 mg 4 tabs HS
100 dosage units = *400* which is *greater* than a 30-day supply (120 tablets)
Rule: sig ≤ TID give a 30-day 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 the disease we know as diabetes mellitus was first described by the Egyptian physician Hesy-Ra in 1552 B.C., in a document known as the Papyrus Ebers? The disease gained the first part of its modern name from the Greek physician Aretaeus of Cappadocia in the first century A.D., who used the term *diabetes* (Greek for "siphon" or "passing through") to describe the condition of patients exhibiting polyuria. *Mellitus* (Greek for "honey" or "honey sweet") was added in 1675 by English physician Thomas Willis in recognition of the fact that the urine of diabetics was known to be sweet, which was later understood to be the result of glycosuria.

PHARMACY FUN

Many, if not most, drugs have more than one indication, and those indications are usually closely related, such as hypertension and heart disease. There are a number of drugs, however, which have been found useful for two or more seemingly unrelated conditions. For each of the following, can you name the one drug that has been used for both of the conditions listed? (Note: many of the secondary indications are off-label uses and may involve different dosage forms) The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. **Hypertension and Hirsutism**
2. **GERD and Warts**
3. **Schizophrenia and Hiccups**
4. **Arthritis and Patent Ductus Arteriosus**
5. **Unwanted Facial Hair and African Sleeping Sickness**
6. **Diabetes and Polycystic Ovary Syndrome**
7. **Angina and Stage Fright**
8. **Bacterial Infections and Syndrome of Inappropriate Antidiuretic Hormone (SIADH)**

Answers to last month's **PHARMACY FUN**:
1. Hubert Humphrey 2. John Keats 3. O. Henry

Photograph by James Murphy