



# Family Medicine Clinical Pharmacy Forum

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*Family Medicine Clinical Pharmacy Forum is a brief bi-monthly publication from the Family Medicine clinical pharmacists distributed to faculty and residents of the Department of Family Medicine. Our intent is to provide timely information on broad-based issues of pharmacotherapy, as well as regulatory and practiced-based issues affecting you as a prescriber. If you have suggestions for things you would like to see, please contact us.*

### Pharmacotherapy Issues.

#### **Tamper-resistant prescription pads for Medicaid patients**

- As a reminder, October 1<sup>st</sup> 2007 is when the CMS regulations go into effect requiring the use of tamper-resistant prescription pads for all Medicaid patients
  - This regulation was buried in the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 and has taken many people by surprise
- To be considered tamper-resistant, prescription pads must contain one of the following industry recognized features (by October 2008, all three features must be met):
  - One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form
  - One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber
  - One or more industry-recognized features designed to prevent the use of counterfeit prescription forms
- Exemptions to the tamper-resistant prescription pad requirement:
  - Electronic prescribing transmissions to the pharmacy
  - Prescriptions which are faxed to the pharmacy
  - Prescriptions called into the pharmacy by the prescriber

<http://www.cms.hhs.gov/SMDL/downloads/SMD081707.pdf>

<http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Tamper.pdf>

#### **New Asthma Guidelines Released**

- In late August, the National Heart Lung and Blood Institute released new guidelines for the Diagnosis and Management of Asthma
  - This is the Expert Panel Report 3 (EPR-3) which builds upon the documents from 1991, 1997, and the 2002 update
  - The guidelines will be similar to the Global Initiative for Asthma (GINA) guidelines released in November 2006
- Only the full report is available at this time; the expected availability of the summary report will be December 2007:

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- <http://public.nhlbi.nih.gov/newsroom/home/GetPressRelease.aspx?id=2442>
- <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm>
- Key features in the new guidelines
  - Assessment and monitoring
  - Patient education
  - Control of environmental factors and other conditions that can affect asthma
  - Medications → continued use of a stepwise approach including expanded pediatric recommendations

### **New Drug:** Budesonide and formoterol (Symbicort®)

Symbicort is a combination of budesonide and formoterol indicated for maintenance treatment of asthma in patients 12 years of age and older. Both agents are FDA-approved as individual therapies. Formoterol is listed under the brand name of Foradil whereas budesonide is Pulmicort. The combination product is very similar to fluticasone and salmeterol combination (Advair) however does not have an indication for COPD.

#### Dosing

- Available in two strengths: 80/4.5 mcg and 160/4.5 mcg (budesonide/formoterol)
- Adults and children ≥ 12 years of age:

Patients receiving medium to high dose corticosteroid	Symbicort 160/4.5, two inhalations twice daily
Patients receiving low to medium dose corticosteroid	Symbicort 80/4.5, two inhalations twice daily
Patients not currently receiving inhaled corticosteroid	Symbicort 80/4.5 or 160/4.5, two inhalations twice daily depending on asthma severity

#### Special Patient Population Info

- Pregnancy category C; caution in breastfeeding (no data)
- Safety and effectiveness has not been established in children <12 years of age

#### Marketplace Assessment

Symbicort will compete directly with Advair for treating asthma patients. The black box warnings are blanket statements by the FDA for long-acting beta<sub>2</sub> agonists and this warning is applied to the combination with inhaled corticosteroids. Symbicort does not have indications for pediatric patients nor is it approved for COPD which is a disadvantage compared to Advair. It is not a dry powder formulation but rather a metered dose inhaler with HFA as the propellant. Cost will be ~\$165-\$190 per month depending on the strength.

-Symbicort® Prescribing Information. AstraZeneca, 2007  
-Drugs 2006;66:2235-2254

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**New Drug:** Zoledronic acid injection (Reclast®)

Zoledronic acid is a bisphosphonate which has been available mainly for the treatment of hypercalcemia by the brand name Zometa®. This formulation is a once-yearly injection indicated for the treatment of osteoporosis in postmenopausal women as well as Paget's Disease.

Dosing:

- Available as a 5 mg/100 ml ready to infuse solution
- It is infused over at least 15 minutes and given once yearly
- It is recommended that all patients be on calcium 1200 mg daily and vitamin D 400-800 IU daily

Adverse Effects:

- Fever/flu-like symptoms, myalgia, arthralgia, and headache which usually resolve within 3 days of the injection but may last up to 14 days
- Acetaminophen or an NSAID following the administration may reduce the incidence of adverse effects
- Of note, osteonecrosis of the jaw is a concerning adverse effect that has been associated with the bisphosphonates; early reports were linked to intravenous formulations however reports exist for the oral formulations as well; associated risk factors include cancer, corticosteroid use, chemotherapy, and poor dentition

Marketplace Assessment:

Less frequent administration of bisphosphonate is not a new concept. Bisphosphonates are taken up into the bone allowing the effect to be prolonged. The oral agents have slowly transitioned into less frequent dosing and now the intravenous formulations will make treatment with these agents even more convenient. Before administering the agent, make sure the payment situation is in place. The estimated cost for injection is \$800.

-Novartis Pharmaceuticals, August 2007

**Short takes**

- **Labeling revisions for ceftriaxone**
  - Revisions to the labeling of ceftriaxone highlighting a potential risk associated with concomitant use of IV Rocephin with calcium or calcium-containing solutions or products
  - Reports of pulmonary precipitation have occurred in neonates receiving both products; although no cases have been reported in patient populations other than neonates, there is a theoretical risk for all patient populations
  - The labeling will now state that ceftriaxone and calcium-containing solutions including continuous calcium-containing infusions such as parenteral nutrition should not be mixed or co-administered to any patient irrespective of age even if different lines are used; based on half-life, administration of ceftriaxone and IV calcium-containing solutions should not be administered within 48 hours of each other in any patient

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- There is no information on a potential interaction between ceftriaxone and oral calcium-containing agents or between IM ceftriaxone and calcium-containing products (oral or IV)  
<http://www.rocheusa.com/products/rocephin/rocephin-hcp-letter.pdf>
- **Medication reconciliation**
  - This is here and will be so everyone needs to get used to it
  - The concept is to reconcile medications being used at home upon admission to the hospital; many times the admitting physician is unclear of what medications the patient is taking or how they are taking them
  - Every facility is working on processes to ensure they are in compliance with JCAHO standards
  - It is up to the physician signing the orders to ensure the patient is taking the medications as prescribed; It is very reasonable to utilize pharmacy and pharmacy students to help with this process not only in the hospital setting but also on the ambulatory side
- **How long do you keep people on Plavix and aspirin?**
  - Many questions arise regarding the length of time patients should remain on the combination of aspirin and Plavix after coronary events; the ACC/AHA updated guidelines have the following recommendations for UA/NSTEMI patients at discharge:
    - Medical therapy without stent: Aspirin 75-162 mg per day indefinitely and clopidogrel 75 mg daily for at least one month and ideally up to one year
    - Bare metal stent: Aspirin 162-325 mg daily for at least one month then 75-162 mg per day indefinitely and clopidogrel 75 mg daily for at least one month and ideally up to one year
    - Drug-eluting stent: Aspirin 162-325 mg daily for at least one 3-6 months then 75-162 mg per day indefinitely and clopidogrel 75 mg daily for at least one year
  - These are minimum recommendations and patients may require longer treatment based on need for anticoagulation versus continued antiplatelet therapy

-J Am Coll Cardiol 2007;50:652-726  
 - <http://content.onlinejacc.org/cgi/reprint/50/7/652>

### Clinical Pearl.

Proper use of per topical permethrin cream rinse (Nix<sup>®</sup>)

- Multiple times we see treatment failures from first line topical agents leading to use of medications such as ivermectin, Bactrim, or more potent topical medications
- Shampooing the hair before applying permethrin is fine however the use of a crème rinse/conditioner or a combination of shampoo/conditioner should

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- NOT be used the hair before applying permethrin as this may decrease the activity of the permethrin
- Also tell patients not to rewash their hair for 1-2 days after applying the permethrin
  - More information including a printable patient handout may be found at the CDC website [www.cdc.gov](http://www.cdc.gov) or here is a link to a PDF document: [http://www.cdc.gov/ncidod/dpd/parasites/lice/2005\\_PDF\\_Treating\\_Head\\_Lice.pdf](http://www.cdc.gov/ncidod/dpd/parasites/lice/2005_PDF_Treating_Head_Lice.pdf)