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PHARMACY MONTHLY NEWSLETTER

AUGUST 5, 2009

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In The News:

FDA approved **Effient® (prasugrel)** despite opposing states from the group Public Citizen just last month voicing an opinion that the drug was unsafe and should not be approved. [[Link](#)]

- ✦ With recent data surfacing regarding a significant interaction between Plavix (clopidogrel) and PPIs, prasugrel represents a potentially significant addition to our armamentarium as it utilizes CYPs that differ from those affected by clopidogrel and most PPIs.

FDA approved **Livalo® (pitavastatin)** for the lowering of cholesterol in patients when TLC is insufficient. It has been approved and marketed in Japan since 2003. [[Link](#)]

- ✦ *See my previous statin review for comparative charts that include pitavastatin* (I was anticipating approval then!) [[Link](#)]
- ✦ Pitavastatin is expected to be available as 1, 2, and 4 mg and potency is similar to Lipitor 10, 20, and 40 mg respectively.
- ✦ Unique qualities include limited CYP metabolism (potentially fewer drug interactions) and HDL increases ranging ~8 % up to ~20 %

Plan B One-Step® (1-pill version of Plan B) and **Next Choice™** (generic version of 2-pill formulations of Plan B) have recently been approved by the FDA. The American College of Obstetricians and Gynecologists (ACOG) released a statement in support of the new 1-step/1-pill version of Plan B while stating that there is NO valid scientific or medical reason to impose an age restriction on the availability of EC[†] because it is safe and effective for adolescents and women of all ages. ACOG again urges the FDA to withdraw the age restriction altogether and eliminate the behind-the-counter status for EC. [[Link](#)]

FDA approves second (US approved) DPP-IV inhibitor, **Onglyza® (saxagliptin)** for T2DM. Importantly, FDA required further cardiovascular safety data (as it will for ALL diabetic drugs hence forth) and saxagliptin did NOT increase CV risk. However, note that data was only from LOW-risk patients and FDA is requiring post-marketing data for HIGH-risk patients. [[Link](#)] [[Link 2](#)]

Tablet Splitting called a “Risky Practice,” unless specifically specified in product labeling, by the FDA. At present, a list of products whose labeling specifies tablet splitting as acceptable is not available. Scored tablets have inferred FDA approval for splitting. [[Link](#)]

Note: Acceptability for tablet splitting should be based upon individual patient circumstances as well as evidence-based OUTCOME studies dealing with the specific drug of concern. For example, referencing a VA study that showed NO undesirable changes in cholesterol levels in tablet splitters as opposed to studies finding unacceptable variation ranges in tablet sizes alone.

[JMCP Article 1](#); [JMCP Article 2](#); [Dept of Veterans Affairs 2003 Study—pub in JMCP](#); Decision Algorithm at www.japha.org

Pharmacy—Clinical Sound Bytes:

- FDA approves (for 1st time) - single ingredient colchicine product (**Colcrys®**) for acute gouty flares and Familial Mediterranean Fever (FMF) in adults and children 4 yrs and older [[Link](#)].
- FDA approves **Onsolis® (fentanyl buccal soluble film)** for breakthrough cancer pain in patients 18 yrs who are already receiving and are tolerant of opioid analgesic; Administration technique and dosing titration table in package insert info [[Link](#)].
- FDA approves **Sumavel™ DosePro™**, a *NEEDLE-FREE* subQ administered sumatriptan [[Link 1](#)], [[Link 2](#)].
- FDA approves **Tyvaso® (treprostinil inhalation)**, prostacyclin vasodilator for pulmonary arterial hypertension in (WHO group 1) in patients with NYHA Class III symptoms, to improve walking distance. [[Link](#)]

Safety Updates:

[Submit ADR[§] to MedWatch Online!](#)

Colcrys® (colchicine) FDA analysis finds that drug interactions affecting the gastrointestinal absorption and/or hepatic metabolism of colchicine play a central role in the development of colchicine toxicity. [Colcrys®](#)
[Xolair®](#)

- Data submitted supporting the safety and efficacy of Colcrys® in acute gout flares demonstrated that a substantially lower dose of colchicine was as effective as the higher dose traditionally used.
- Patients receiving lower dose experienced significantly fewer ADRs compared w/ higher dose.

[Ask RPh to submit ADR to Medwatch](#)

FDA issues early ongoing safety analysis re: **Xolair® (omalizumab)** regarding data from the EXCELS study that suggests an increased number of cardiovascular and cerebrovascular ADRs in a group of patients using Xolair® compared to control group.

- Link to ALL June 2009 [labeling changes](#) (i.e., post-marketing ADR updates) [[Link](#)]

* *Example: Amaryl® (glimepiride) updated drug information to include ‘Drugs that may potentiate the hypoglycemic action of sulfonylureas: disopyramide, fluoxetine, and quinolones’ in drug interactions section.*

New Generic Approvals*:

[Each have a Medicare exception from Tier changes until 1/1//2010]

Levalbuterol, generic Xopenex® nebulizer; **Doxycycline Monohydrate**, generic for Doryx®; **minocycline** generic for Solodyn®; **malathione**, generic for Ovide®; **alprazolam ODT**, generic for Niravam®.

Others recently include: Ortho-Tri-Cyclen LO, Topamax, Adderall XR, Vivactil, Tobradex





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Emerging Therapies & the Drug Pipeline:[Daxas](#)

Chronic Obstructive Pulmonary Disease (COPD)—Daxas® (roflumilast) is a phosphodiesterase 4 (PDE4) enzyme inhibitor. PDE4 is believed to play a significant role in the targeting cells and mediators of the COPD disease process. Daxas potentially represents the first in a new class of COPD medications, and the first new class of medications for COPD in approx 20 yrs. The recent NDA[†] submission is based on encouraging results from four Phase III trials of Daxas (roflumilast) in the treatment of symptomatic COPD.

- Two pivotal 12-month studies showed positive effects on exacerbation rates and pulmonary function (FEV₁).
- Two supporting six-month studies also confirmed the efficacy of Daxas® when used with standard bronchodilator treatments. Full data from all four studies are to be published during 2009.


Pharm.D. Monthly Q&A Review:**Incoming e-mail Question:**

“Can Melleril (thioridazine) cause hyponatremia”

Excerpt of Outgoing e-mail Answer:

- **Yes**, it can infrequently cause SIADH and/or hyponatremia. Potential mechanism include causing extreme dry mouth and excessive thirst with potential result of hyponatremia. Additionally, thioridazine is infrequently associated with hyperpyrexia which could also lead to sodium loss and potential hyponatremia.

Disease State Or Literature Update:**Guideline Update on Rhinitis**

[Rhinitis Guidelines](#)
[Amox/Clav in Pediatrics](#) 

Key Updates Include:

- ⊕ Pharmacologic products introduced since publication of the 1998 “Diagnosis and Management of Rhinitis: Complete Guidelines”
- ⊕ More defined positioning of agents (e.g., leukotriene receptor antagonists) in management based on more recent evidence
- ⊕ ‘episodic’ as a term to describe rhinitis elicited by sporadic exposures to inhalant aeroallergens, & implications for treatment
- ⊕ **Use of certain agents—that is, intranasal corticosteroids—on an as needed basis**
- ⊕ Emphasis on recognizing comorbidities of allergic rhinitis (AR) such as asthma, sinusitis, and obstructive sleep apnea and conducting appropriate studies, such as pulmonary function testing and sleep apnea studies
- ⊕ Evidence on using **combination therapy**, specifically leukotriene receptor antagonists with antihistamines
- ⊕ Need to consider the benefits vs. recently raised safety concerns about oral decongestants before their use in children below age 6 yrs
- ⊕ Recommendation of considering **2nd generation antihistamines as safe agents for use during pregnancy**
- ⊕ Use of intranasal corticosteroids for symptoms of allergic conjunctivitis associated with rhinitis
- ⊕ Consideration of using a Rhinitis Action Plan
- ⊕ Emerging diagnostic and surgical procedures, such as acoustic rhinometry and radiofrequency volumetric tissue reduction

Related Recent Study—Amox/Clav for acute sinusitis

- Children receiving the antibiotic were more likely to be cured (50% vs 14%) and less likely to have treatment failure (14% vs 68%) than children receiving the placebo.
- There were previously only 2 randomized, placebo-controlled studies that have examined the efficacy of antibiotic therapy in children diagnosed with ABS. One used amox/clav and found benefit while the other used amoxicillin only and did NOT find benefit.

Formulary Updates: Updated June 2009

Tier changes: ~~As of 8/1/2009, Lipitor® moved from Tier 2 to be non-formulary and Tier 3~~

Tier Revisions due to availability of generic products:

Brands moved to Tier 3; Topamax/Topamax sprinkle, Cytomel, Depakote ER sprinkles, Imitrex, Tegretol XR, Tindamax, Adderall XR, Cellcept, Risperdal M-tab; All those Generics to Tier 1.

Brands to Tier 3 but generics also to Tier 3; Doryx, Solodyn, Xopenex, Ovide, Niravam

Additions: Astepro, Acanya added to Tier 2.

Afinitor, Vectical, Seroquel/Seroquel XR added to Tier 2 w/ PAR (exceptions)

REMOVAL of Prior Authorization (PAR) requirements: Topamax

Reviewed by P+T/Remain non-preferred: Epiduo, Kapidex, Uloric, Savella, Zylet, Rapaflo, Akten, Nuvigil, Ryzolt, Edular, Exforge HCT, Allernaze, Gelnique.

[Link to IHA Formulary](#) [Tablet Splitting Program](#) 