



PHARMACY MONTHLY NEWSLETTER

JULY 1, 2009

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In The News:

Lantus and risk of cancers? Diabetologia published a series of articles examining a potential increase in risk of cancer in patients on insulin, particularly those on Lantus (glargine). This info does NOT prove that insulin (glargine in particular) increases cancer risk.

- The studies only suggest that a closer look with prospective randomized studies is warranted.
- The studies published are NOT all in agreement.
- The studies do NOT agree that one insulin is more likely than another.

[EASD Helpful Links](#)
[EASD—Info for Patients](#)
[Diabetologia Articles](#)

The FDA has approved an alternative to the widely used Afib drug amiodarone. **Multaq (dronedarone)** has been approved to help maintain normal heart rhythms in patients with Afib or atrial flutter. It will carry a black box warning which warns of death in patients with recent severe heart failure. Amiodarone carries its own black box warning.

- Dronedarone is expected to cause **fewer** toxicities to the thyroid and nervous system due to lack of iodine component in its structure and less lipophilicity than amiodarone with similar efficacy. [[Link](#)]

Acetaminophen combos banned by FDA panel, stricter labeling requirements of any APAP containing product? Information from the public advisory committee meeting June 29-30 here: [[Link](#)]. FDA information for patients regarding liver injury and APAP [[pdf Link](#)]

Should certain **antidepressants (CYP2D6 inhibitors)** should be avoided during chemo therapy with **Tamoxifen**? New study presented at the American Society of Clinical Oncology's (ASCO) annual meeting questions CYP2D6 is interactions mechanism [[Link](#)]

- **Note:** Femara (letrozole) is only partially metabolized via CYP2D6 (mainly 3A4); [[Link to CYP Interaction Chart](#)]
- Patient and Physician tamoxifen information guide [[pdf Link](#)]

Re: Combining anti-clotting agents; A study utilizing data from the Veterans Dept Affairs; Among the 78,000 patients (aged 60-99 yrs) identified, 30% were prescribed 2 or more anti-clotting agents. Within 1 year, over 1,000 of these patients required immediate medical attention for an upper gastrointestinal event (e.g., bleeding or perforation). The least risky combination, warfarin plus an antiplatelet drug (e.g., clopidogrel), **increased the risk of a GI event by 70%**. Aspirin plus an antiplatelet drug doubled the risk of an upper GI event, while aspirin plus an anticoagulant tripled the risk. Using 3 antithrombotic agents was linked to a **4-fold INCREASE** in risk. [[Link 1](#)],[[Link 2](#)]

Pharmacy—Clinical Sound Bytes:

- Newly FDA approved drugs—**Cambia** (diclofenac potassium for oral solution) [[Link](#)]; **Zipsor** (diclofenac potassium) liquid filled capsules [[Link](#)]; **Ozurdex** (dexamethasone intravitreal implant) [[Link](#)]; **Caldolor** (ibuprofen) injection (for IV use) [[Link](#)]; **Besivance** (besifloxacin oph susp) [[Link](#)]; **Simponi** (Golimumab) monthly inj approved by FDA for rheumatoid and active psoriatic arthritis and ankylosing spondylitis [[Link](#)]
- The group Public Citizen claims **Effient (prasugrel)** is unsafe and should NOT be approved. **Note:** In Feb 2009, the FDA Advisory Panel voted unanimously in favor of approving the drug. The FDA itself has yet to make a final decision on this drug. [[Link](#)]
- More data for **Red Yeast Rice** [[Link](#)]

Safety Updates:

Lantus/insulins® as above and FDA link to right—>

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



[Submit ADR^s to MedWatch Online!](#)

[Lantus® FDA](#)
[Zicam™](#)
[Levemir®](#)
[Chantix/Zyban](#)

Zicam™ and long-lasting or permanent loss of sense of smell; FDA recommends that patients who have Zicam Nasal Gel, Nasal Swabs, Swabs, and Kids Size stop using these products and discard. Since 1999, the FDA has received over 130 reports of anosmia associated with the use of Zicam zinc-containing intranasal products.

- This advisory does NOT apply to zinc tablets and lozenges taken by mouth.

Chantix® (varencline) and **Zyban®** (bupropion) both receive black box warnings for behavioral changes ranging from depression to suicidality. Analysis is ongoing and the drug companies are now required to conduct safety studies.

Levemir®, a few lots of stolen vials re-enter the market (lots include: XZF0036, XZF0037, and XZF0038). FDA advises that patients NOT use insulin from these lots and reminds us that Levemir should be a clear and colorless solution.

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

* Example; **Lipitor® (atorvastatin)** updated drug information to include 'hepatic failure' in adverse reaction section.

New Generic Approvals*:

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

Tri Lo Sprintec (ethinyl estradiol/norgestimate), generic for Ortho-Tri-Cyclen LO now available.

Other drugs that have recently become available generically: Topamax, Adderall XR, Vivactil, Tobradex





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Emerging Therapies & the Drug Pipeline:

[Cetriad](#)

Mixed Dyslipidemia—Cetriad® (rosuvastatin/fenofibric acid) is a new combination tablet for dyslipidemia is making its way through the FDA approval process. If approved it will be the first combination of a fibrate and a statin to hit the market. Recent, increased focus on complete lipid control by NCEP & AHA, they encourage such therapeutic combinations (with available products). Fenofibric acid (Trilipix®) is the only fibrate to gain FDA approval for combination with a statin. Thus approval of this product seems likely. As usual, cost will be the large consideration for P + T committees and the like for the drug to become useful.

Note: Niaspan ER® (niacin) remains the most effective in raising HDL, and does so regardless of TG level. Fenofibric acid and other fibrates are typically only effective in raising HDL when TGs are also significantly off target. In addition, it's apparent that gemfibrozil is much more likely to cause myalgias in combination with a statin, as well as alone compared with fenofibrate.

Pharm.D. Monthly Q&A Review:

[EuroSCAR Study](#)

Incoming e-mail Question:

"I have a patient who suffered Stevens Johnson's Syndrome (SJS) following Protonix (pantoprazole) initiation —only med pt is on— does this rule out ALL PPIs for this patient?"

Excerpt of Outgoing e-mail Answer:

Yes. However, there is some potential evidence that Protonix may be more likely to cause SJS or TEN. On the other hand, it also appears that ALL PPIs have been implicated at least in case report or potential association. The chemical structure of all PPIs uses a sulfur group (not sulfonamide though) as their active group to interact with H⁺ and the ATPase pump in the stomach. I don't see any reason from a structural standpoint that Protonix would be any more likely than another PPI.

EuroSCAR study:

- [Pantoprazole was also associated with a significant univariate RR (uvRR), but without a clear pattern of "highly suspected" drugs in terms of timing and co-medication. *No association was observed with other proton pump inhibitors.*]

Disease State Or Literature Update:

Cholesterol and Lipids—Lipoprotein(a) [Lp(a)]

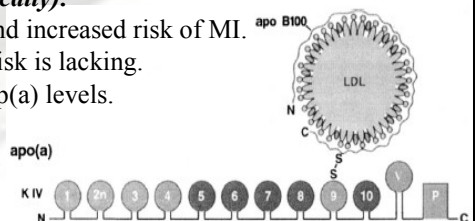
Lp(a) is thought of as another atherogenic lipoprotein but is NOT yet well understood. Like LDL, each Lp(a) particle has one molecule of apolipoprotein B-100. The apolipoprotein(a) component of Lp(a) is structurally similar to plasminogen, but it has NO fibrinolytic properties and likely interferes with the physiologic role of plasminogen.

- Increases (> 30 mg/dL) in Lp(a) are associated with increases in the risk of CAD.
- However, general screening for Lp(a) is currently NOT recommended.
- Furthermore Lp(a):
 - * Unaffected by diet or exercise
 - * Benefit from lowering Lp(a) not yet proven
 - * Decreased by — Niacin, Estrogen, Genetics [NOT statins or other antihyperlipidemics]

[JAMA article abstract](#)
[Niacin and Lp\(a\)](#)
[COMPELL Study](#)

Recent study published in JAMA supported Lp(a) as a causal link in CV disease (MI specifically):

- Elevated Lipoprotein(a) demonstrated a causal association between elevated levels of it and increased risk of MI.
- To date, published literature on interventions reducing Lp(a) levels and reduction of CV risk is lacking.
- However, it is notable to mention that niacin is an intervention that significantly lowers Lp(a) levels.
- In contrast, statins have either not impacted or actually raised Lp(a) levels.
 - COMPELL Study showed that atorvastatin and rosuvastatin both increased Lp(a) levels when used alone, decreases in Lp(a) were seen ONLY when used WITH niacin



Formulary Updates:

Tier changes:

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

(Crestor® still tier 2)

Moved from Tier 2 to Tier 1: QVar®

Removal of Prior Authorization requirements:

Prandin, Prandimet, Ranexa, Suboxone, Janumet, Januvia

Additions:

Promacta, Banzel, Vimpat, Xenazine all added to Tier 2 w/ PAR; Prandimet, Apriso both added to Tier 2

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