



PHARMACY MONTHLY

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NEWSLETTER

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In The News:

Vytorin and Cancer? A recent analysis of the SEAS study unexpectedly found an increased risk of cancer and deaths from cancer in patients taking Vytorin®, compared with those given a placebo. The researchers, using data on 20,000 patients from two other continuing Vytorin studies (IMPROVE-IT, SHARP), said the study's suggestions of a link to cancer is largely due to chance and "implausible." Unfortunately conclusions can not yet be drawn on Vytorin's safety.

- * NOTE: numerous other combinations of cholesterol medications w/statins have shown to be safe and effective (Niaspan, Welchol, etc)
- * These results should serve to re-enforce need to maximize statin dose and encourage lifestyle modifications.
- * Perhaps also illustrating need to capture entire lipid profile, not just pushing LDL.

eAG vs. A1c? In effort to make A1C and 'average glucose' readings more meaningful to patients, ADA and others are beginning a push to speak in terms of Estimated Average Glucose (eAG) over A1c verbage. Goal of A1c <7% becomes eAG of <154mg/dL. Currently CHS Labs do NOT report eAGs, however, if you wish to estimate it: [eAG = 28.7 x A1c - 46.7].

Stats for Children? American Academy of Pediatrics is causing a stir with new lipid screening guidelines. Guidelines say to screen high risk children (based on family history) after age 2 but before age 10, then every 3—5 years. AAP advises pharmacologic treatment (mainly statin-based) in children ≥8yrs w/persistent LDL elevations and high risk. Long term safety data for statin use in children does NOT yet exist. Debate is ongoing.

Exforge® (amlodipine/valsartan - 3rd tier/PAR required IHA drug) gained an indication for initial therapy for patients likely to require multiple drugs to meet to BP goals. Amlodipine, amlodipine/benazepril (both 1st tier) and Diovan® (2nd tier) as separate rx's likely less expensive for patient, though NOT in ALL cases.

- [Vytorin](#)
- [SEAS Press Release](#)
- [SEAS Debate](#)
- [ADA and eAG](#)
- [ARBs & Alzheimers](#)
- [AAP Lipids](#)
- [ADA Lipids](#)
- [Exforge](#)

Safety Updates:

Submit ADR^s to MedWatch Online!



- FDA mandated that **fluoroquinolone antibiotics** receive a black box warning for increasing risk of tendonitis & tendon rupture, in addition to development of a med guide. Risk is still small, ~ 1 in 10,000, but here is 3-4 times greater w/quinolones. Risk is highest for those >60 yrs of age, on corticosteroids, or kidney/heart/lung transplants. At this point, be vigilant w/quinolone use and d/c when possible if joint tenderness arises.
- FDA required black box warnings be added to BOTH **conventional and atypical antipsychotics** indicating that they are associated with an **increased rate of death** when used for age-related psychosis.

- [Quinolones](#)
- [Antipsychotics](#)

Ask Rph to submit ADR to Medwatch



New Generic Approvals*:

- **Albuterol Inhalers**—Help affording HFA inhalers is available. Low-income and copay assistance programs.
- **Lamotrigine**, generic for Lamictal®, in all strengths, both regular tabs and dispersible tablets. Lamotrigine indicated as adjunctive therapy as young as ≥2 yrs and older in specific situations, as monotherapy conversion from another antiepileptic, and for Bipolar I maintenance. (While FDA just expanded patent on **Topamax®** to March 2009)
- **Divalproex sodium delayed release tab**, generic for Depakote®; indicated to treat seizures, bipolar & migraines.
- **Dronabinol**, generic for Marinol®, indicated for nausea and vomiting due to cancer/chemotherapy in patients who've failed to response to conventional treatments.
- **Zalepon**, generic for Sonata®, indicated for short term treatment of insomnia. NOT shown to increase sleep duration.

- [Transition Now Help](#)
- [Proventil HFA](#)
- [ProAir HFA](#)
- [RxAssist.org](#)
- [InhalerTransition.org](#)
- [Lamotrigine](#)
- [Topamax](#)
- [Divalproex sodium](#)
- [Dronabinol](#)
- [Zalepon](#)

Emerging Therapies & the Drug Pipeline:

- **Alzheimer's related: Rember®**, Tau accumulation inhibitor. (TauRx) early results indicate that the drug may halt progression of disease, no marketed drug can yet show, by preventing accumulation of Tau proteins & dissolving neurofibrillary tangles.
- **Oral Anticoagulants: Xarelto** (selective Xa inhibitor), **Pradaxa** (direct thrombin inhibitor) already marketed in Europe.

- [TauRx](#)
- [Rember](#)
- [Xarelto](#)
- [Pradaxa](#)

Disease State Or Literature Update:

[Full Text PDF](#)

Lifestyle vs. Statin: Mayo Clinic Study shows 40% drop in LDL-C for BOTH intensive lifestyle modifications (LMs) and simvastatin 40mg. LMs included 3½ hr meeting/week for 12 weeks of intensive EDUCATION on nutrition, exercise & relaxation. This group also took fish oil & Red Yeast Rice (RYR) (600mg bid). Initial baseline LDL's were similar at around 155mg/dL for each group, and average age of LM group was 55.9yrs whereas simvastatin group age was 59.3yrs.

Study demonstrates plausible significant cholesterol reductions using LMs together w/alternative medications. However, durability & feasibility of such a program utilized in primary care remains to be seen (in other words, this IS clear with statins). Also, highest risk patients will most likely be older than studied here, unlikely to contribute significant exercise or break old habits. Clearly, LMs should still be part of primary strategy. RYR contains active component that structurally resembles lovastatin, thus similar risks for ADRs apply. In addition, FDA does NOT regulate content of OTC RYR products, thus large variations in response should be expected.

The LMs were educational only, no direct observation of diet/exercise/relaxation appeared to take place, questioning the value that study results would add to LMs, fish oil, or RYR taken alone.

Formulary Updates:

Status Changes: erythromycin/benzoyl peroxide moved to tier 1; Lacrisert®, Cymbalta®, Opana® ER added to tier 2

Changes based on availability of generic products: Kytril®, Requip®, Coly-Mycin M®, and Sarafem® moved to tier 3

Reviewed at last P&T; will remain non-preferred (Tier 3): Pristiq®, Patanase®, Treximet®, Omnisar™ and Amrix®

[Link to IHA Formulary](#)



*All meds tier 1 unless otherwise specified; §ADR = Adverse Drug Reaction