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# **A<sup>PhA</sup>** **DrugInfoLine<sup>®</sup>**

**September 2018**

## [OTC Medicines Corner](#)

Advising on this article: Tara Whetsel

**September 4, 2018**

# **One-dose-fits-all approach to aspirin therapy for primary prevention is not ideal**

## **Key Point**

The benefits of aspirin therapy appear to be dose dependent, with patients of higher body weight (>70 kg) requiring higher doses to prevent cardiovascular (CV) events, and similar results observed for the long-term reduction in the risk of colorectal cancer, according to results of a meta-analysis published in the Lancet.

## **Source URL:**

<http://www.aphadruginfoline.com/otc-medicines-corner/one-dose-fits-all-approach-aspirin-therapy-primary-prevention-not-ideal>

## [Focus on Lipids Care](#)

Advising on this article: Amber L. Briggs

**September 4, 2018**

# **Lipid-lowering benefits on clinical outcomes relative to baseline LDL value**

## **Key Point**

A meta-analysis published in JAMA of 34 trials involving more than 270,000 patients showed that more intensive LDL-lowering therapy compared with less-intensive therapy resulted in a greater reduction in the risk of all-cause and cardiovascular (CV) mortality, but only in patients with baseline LDL levels of 100 mg/dL or more.

## **Source URL:**

<http://www.aphadruginfoline.com/focus-lipids-care/lipid-lowering-benefits-clinical-outcomes-relative-baseline-ldl-value>

## [Nephrology](#)

Advising on this article: Edward F. Foote, Sarah Ray

**September 11, 2018**

# **Apixaban is an option for anticoagulation in patients on dialysis**

## **Key Point**

Use of standard-dose apixaban (Eliquis—Bristol-Myers Squibb, Pfizer) in patients with atrial fibrillation (AF) and end-stage renal disease (ESRD) who are on dialysis was associated with a significantly lower risk of stroke/embolism, death, and major bleeding compared with warfarin, according to results of an observational study published in *Circulation*.

## **Source URL:**

<http://www.aphadruginfoline.com/nephrology/apixaban-option-anticoagulation-patients-dialysis>

## [Focus on Diabetes Care](#)

Advising on this article: Charles D. Ponte

**September 11, 2018**

# **Sulfonylureas as second-line agents increase the risk of adverse outcomes**

## **Key Point**

Adding sulfonylurea to metformin therapy or switching metformin to a sulfonylurea in patients with type 2 diabetes resulted in an increased risk of myocardial infarction (MI), all-cause mortality, and severe hypoglycemia compared with metformin monotherapy, according to results of an observational study published in BMJ.

## **Source URL:**

<http://www.aphadruginfoline.com/focus-diabetes-care/sulfonylureas-second-line-agents-increase-risk-adverse-outcomes>

## Alerts and Recalls

### Generic Name (Trade Name—Company)

September 4, 2018

### Montelukast

**(No trade name—Camber Pharmaceuticals)**

**Bottles labeled as montelukast contain different drug**

### Uses/Notes

[FDA is warning](#) consumers and health professionals about a voluntary recall of one lot of montelukast sodium tablets (lot #MON17384, expiration 12/31/2019) by Camber Pharmaceuticals. Sealed bottles labeled as montelukast sodium tablets, 10 mg, 30-count bottle were found to instead contain 90 tablets of losartan potassium tablets, 50 mg.

This tablet mix-up may pose a safety risk because taking losartan tablets when not prescribed has the potential to cause renal dysfunction, elevated potassium levels, and low blood pressure. This risk is especially high for pregnant women taking the allergy and asthma medication montelukast because losartan, which is indicated to treat high blood pressure, could harm or kill the fetus.

FDA recommends that consumers who have this recalled product contact their health care provider or pharmacist immediately.

Montelukast sodium tablets are beige, rounded square-shaped, film coated tablets that are imprinted with “I” on one side and “114” on the reverse. Losartan tablets are white and oval-shaped with the letter “I” imprinted on one side and the number “5” imprinted on the reverse.

This recall is not related to the recent valsartan recalls that were due to an impurity, *N*-nitrosodimethylamine (NDMA).

To date, Camber has not received adverse event reports associated with this recall.

### Source URL:

<http://www.aphadruginfoline.com/alerts-and-recalls/bottles-labeled-montelukast-contain-different-drug>



## [New Drug Approvals](#)

### Generic Name (Trade Name—Company)

September 4, 2018

### **Doravirine, lamivudine, tenofovir disoproxil fumarate; doravirine**

### Uses/Notes

[Merck announced](#) FDA approval of two new HIV-1 medications for adult patients with no prior antiretroviral treatment experience: a once-daily fixed-dose combination tablet of doravirine 100 mg, lamivudine (3TC) 300 mg, and tenofovir disoproxil fumarate (TDF) 300 mg, approved under the trade name Delstrigo; and doravirine 100 mg, a new nonnucleoside reverse transcriptase inhibitor that is administered in combination with other antiretroviral medicines and was approved under the trade name Pifeltro.

Both drugs are administered orally once daily with or without food.

Approval was based on findings from two pivotal, randomized, multicenter, double-blind, active controlled Phase III trials, DRIVE-AHEAD and DRIVE-FORWARD.

Delstrigo is contraindicated in patients with a previous hypersensitivity reaction to 3TC.

Delstrigo and Pifeltro are contraindicated when coadministered with drugs that are strong CYP450 3A enzyme inducers because significant decreases in doravirine plasma concentrations may occur and lessen their effectiveness.

Immune reconstitution syndrome can occur, including autoimmune disorders with variable time to onset, which may necessitate further evaluation and treatment.

Renal impairment, including acute renal failure and Fanconi syndrome, has been reported with use of TDF. Delstrigo should be avoided with concurrent or recent use of a nephrotoxic agent, as cases of acute renal failure after initiation of high-dose or multiple NSAIDs have been reported in patients with risk factors for renal dysfunction who appeared stable on TDF.

Common adverse reactions in clinical trials included dizziness (7%), nausea (5%) and abnormal dreams (5%).

Delstrigo and Pifeltro do not cure HIV-1 infection or



**(Delstrigo; Pifeltro—Merck)**

AIDS.

**FDA approves two new HIV-1 medications**

**Source URL:**

<http://www.aphadruginfoline.com/new-drug-approvals/fda-approves-two-new-hiv-1-medications>

## Alerts and Recalls

### Generic Name (Trade Name—Company)

September 11, 2018

### Dolutegravir-containing medications

*(Tivicay, Juluca, Triumeq—ViiV Healthcare)*

### FDA warns of potential risk of neural tube birth defects with dolutegravir

### Uses/Notes

[FDA is alerting](#) the public that serious cases of neural tube birth defects involving the brain, spine, and spinal cord have been reported in babies born to women treated with dolutegravir, an antiretroviral medication used to treat HIV. Approved in 2013, dolutegravir has been on the market for 5 years and is available as a single-ingredient product under the brand name Tivicay and as a fixed-dose combination tablet with other HIV medications under the brand names Juluca and Triumeq.

Preliminary results from an ongoing observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appeared to be at higher risk for these defects.

Health professionals should inform women of childbearing age about the potential risk of neural tube defects when a dolutegravir-containing regimen is used at the time of conception and early in pregnancy.

Patients should not stop taking dolutegravir without first talking to their health professional because stopping the medicine can cause the HIV infection to worsen. Stopping dolutegravir without first talking to a prescriber can cause the HIV infection to become worse.

More information is available on FDA's [website](#).

To date, in this observational study there are no reported cases of babies born with neural tube defects to women starting dolutegravir later in pregnancy. FDA said it is investigating this new safety issue and will update the public when it has more information. Ongoing monitoring will continue as part of the observational study in Botswana.

### Source URL:

<http://www.aphadruginfoline.com/alerts-and-recalls/fda-warns-potential-risk-neural-tube-birth-defects-dolutegravir>

## [Alerts and Recalls](#)

### Generic Name (Trade Name—Company)

September 11, 2018

### Multiple generic names

***(Multiple trade names—Beaumont Bio Med Inc.)***

**FDA alerts consumers to voluntary recall of Beaumont Bio Med's homeopathic products**

### Uses/Notes

FDA is alerting consumers and health professionals to a voluntary [recall](#) of all water- and alcohol-based Beaumont Bio Med Inc. (Grand Rapids, MI) drug products. These products, labeled as homeopathic, are being recalled due to microbial contamination at the manufacturing facility.

Administration or use of drug products with microbial contamination could result in increased infections that may require medical intervention or be life-threatening to certain individuals.

These products were manufactured at the [King Bio, Inc.](#), facility in Asheville, NC. Previously, [FDA alerted consumers to HelloLife's voluntary recall of drug products labeled as homeopathic](#), also manufactured by King Bio.

### Source URL:

<http://www.aphadruginfoline.com/alerts-and-recalls/fda-alerts-consumers-voluntary-recall-beaumont-bio-meds-homeopathic-products>

## Supplemental Approvals

### Generic Name (Trade Name—Company)

September 11, 2018

### **Buprenorphine and naloxone**

**(Cassipa—Teva)**

**FDA approves new sublingual formulation for maintenance treatment of opioid dependence**

### Uses/Notes

FDA has [approved](#) buprenorphine and naloxone sublingual film under the trade name Cassipa for maintenance treatment of opioid dependence. This action provides a new dosage strength (16 mg/4 mg) of the sublingual film, which is also approved in both brand name and generic versions and in various strengths.

Cassipa should be used as part of a complete treatment plan that includes counseling and psychosocial support and should be used only after patient induction and stabilization up to a dose of 16 mg of buprenorphine using another marketed product.

Common adverse events are oral numbness, burning mouth, inflammation of oral mucous membrane, headache, nausea, vomiting, excessive sweating, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema.

These products may only be prescribed by Drug Addiction Treatment Act–certified prescribers.

### Source URL:

<http://www.aphadruginfoline.com/supplemental-approvals/fda-approves-new-sublingual-formulation-maintenance-treatment-opioid>

## [Supplemental Approvals](#)

### Generic Name (Trade Name—Company)

September 11, 2018

### Riluzole oral suspension

*(Tiglutik—ITF Pharma)*

**First easy-to-swallow riluzole liquid approved for treatment of ALS**

### Uses/Notes

FDA has [approved](#) riluzole oral suspension for the treatment of amyotrophic lateral sclerosis (ALS). It is the first and only easy-to-swallow thickened riluzole liquid for ALS and is administered twice daily via an oral syringe.

Approval was based on bioavailability studies comparing oral riluzole tablets to riluzole oral suspension. While riluzole's mechanism of action is not fully understood, in clinical studies it has been shown repeatedly to modulate glutamate neurotransmission by inhibiting both glutamate release and postsynaptic glutamate receptor signaling.

The most common adverse effects of the oral suspension are consistent with the established clinical profile of riluzole and include oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension, and abdominal pain.

Riluzole oral suspension has received orphan drug designation from FDA. The product will be available in mid-October.

### Source URL:

<http://www.aphadruginfoline.com/supplemental-approvals/first-easy-swallow-riluzole-liquid-approved-treatment-als>

## [Alerts and Recalls](#)

### Generic Name (Trade Name—Company)

September 11, 2018

### Multiple generic names

***(Multiple trade names—Pharm D Solutions)***

**Pharm D Solutions recalls all sterile compounded drug products**

### Uses/Notes

Pharm D Solutions is voluntarily [recalling](#) all sterile compounded drug products dispensed with the past 12 months because of concerns that practices at the pharmacy may pose a risk of contamination to products intended to be sterile. These concerns arose following a routine inspection of the pharmacy by FDA.

Administration of a nonsterile product that is intended to be sterile by S.C., I.M., I.V., or ocular routes of administration may result in serious injury or death.

Pharm D Solutions stated that to date, it is not aware of any adverse events related to this recall nor any indication that the compounded sterile drug products being recalled are actually contaminated. No medications or any component thereof have been shown to be nonsterile.

The recall encompasses all compounded sterile drug products, within expiry, that were dispensed within the last twelve months. The sterile drug products subject to this recall were distributed nationwide and directly to customers and/or medical facilities. The recall does not affect the pharmacy's nonsterile compounded products or retail pharmacy operations.

### Source URL:

<http://www.aphadruginfoline.com/alerts-and-recalls/pharm-d-solutions-recalls-all-sterile-compounded-drug-products>

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