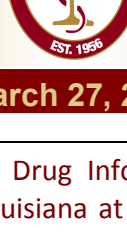


FYDI
FOR YOUR DRUG
INFORMATION



March 27, 2014

ULM
COLLEGE OF PHARMACY
Drug Information Center



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Greetings from the Drug Information Center at the University of Louisiana at Monroe College of Pharmacy!

We hope you find this newsletter helpful in staying well-informed.

Please contact us and let us assist you with any drug information needs, such as full-text article retrieval. In this issue, find out more about the services the DIC has to offer.

In this issue...

FDA MedWatch and Other Safety Alerts

News Items

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FDA MedWatch and Other Safety Alerts

Access to full-text articles may require subscription. Contact the Drug Information Center for literature retrieval assistance.

Drug Recall: Pleo Homeopathic Drug Products

Tera Medica has announced a voluntary recall of some lots of Pleo Homeopathic drug products due to probable presence of penicillin.
[View Recall](#)

Product Recall: Freestyle and Freestyle Flash Glucometers

Abbott Diabetes Care has recalled Freestyle and Freestyle Flash glucose testing meters due to possible abnormal low readings when testing blood glucose with Abbott Freestyle test strips.
[View Recall](#)

Drug Recall: Reufoman Plus Tablets

The FDA has issued a warning stating some lots of Reufoman Plus tablets, marketed as dietary supplements for pain relief, contain undeclared active ingredients that are potentially harmful to patients.
[View Alert](#)

Drug Recall: Custom Procedural Tray/Kit, 1% Lidocaine HCl Injection, USP, 10 mg/mL

Hospira, Inc. has recalled one lot of lidocaine product due to confirmed customer reports of visible particulates.
[View Recall](#)

Drug Safety: Azithromycin/Levofloxacin

A recent study published by the Annals of Family Medicine suggests that azithromycin and levofloxacin are associated with cardiac arrhythmias and death.
[View Alert](#)

Drug Recall: Atorvastatin Calcium (Ranbaxy Product)

Ranbaxy Laboratories Ltd has recalled some batches of generic Lipitor due to product mislabeling that may result in possible overdose and serious side effects in patients.
[View Alert](#)

Drug Safety Alert: Doribax

The FDA issued a warning about the use of Doribax (doripenem) to treat pneumonia in mechanically ventilated patients.
[View Alert](#)

Drug Recall: Dianeal PD-2 Peritoneal Dialysis Solution

The FDA announced Baxter's voluntary recall of Dianeal PD solution with 1.5% Dextrose due to contamination with mold.
[View Alert](#)

Drug Recall: Pfizer's Effexor XR 150 mg and Greenstone's Venlafaxine HCL 150 mg ER Capsules

The FDA announced voluntary recall of two lots of Effexor XR 150 mg capsules by Pfizer and one lot of venlafaxine 150 mg capsules by Greenstone due to possible packaging adulteration with Tikosyn capsules.
[View Alert](#)

Drug Recall: Etomidate Injection by Pfizer-Mylan

The FDA has issued a voluntary recall for Etomidate injection due to presence of particulates and improper labeling.
[View Alert](#)

Drug Recall: L-citrulline by Medisaca

The FDA has announced that certain lots of L-citrulline have been recalled due to subpotency.
[View Alert](#)

Drug Recall: Weight Reducing Formulas by MyNicKnox

MyNicKnox and FDA announced the recall of Fruta Planta weight loss formula due to harmful active ingredients found in some manufactured lots.
[View Alert](#)

Drug Recall: Acetylcysteine Solution 10% by Roxane

The FDA announced a voluntary recall of acetylcysteine due to the presence of glass particles in the solution.
[View Alert](#)

Drug Safety Communication: Saxagliptin

The FDA is investigating the risk of developing heart failure in patients with type 2 diabetes taking saxagliptin, a DPP-4 inhibitor.
[View Alert](#)

Calcium Gluconate 10% Injections Made by Rx Formulations Recalled

Rx Formulations is recalling one lot of calcium gluconate injection due to microbial contamination.
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[Medwatch Voluntary Reporting Form](#)

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News Items

Hemoglobin A1c Offers No Significant Benefit in Cardiovascular Risk Outcomes

A new study suggests that additional assessment of HbA1c offers little or no benefits to cardiovascular risk prediction.
[View Study](#)

Widely Used Liquid Nicotine for E-Cigarettes Leads to Increased Adverse Events

The increased popularity of non-FDA regulated e-cigarettes for smoking cessation has led to an increase in accidental poisonings and adverse effects in children and adults due to the very potent e-liquid that can be harmful whether ingested or absorbed through the skin.
[View Item](#)

Ceftriaxone Linked to Acute Renal Failure in Pediatrics

Pediatrics Acute Renal Failure has been associated with the use of ceftriaxone according to recent study.
[View Abstract](#)

Phenylephrine and Acetaminophen Combo May Cause Serious Adverse Effects

According to a new study, acetaminophen increases phenylephrine blood levels four times higher and may lead to serious adverse effects including high blood pressure, dizziness, and tremors.
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Statin May Help Slow Progression of Secondary Multiple Sclerosis

New research suggests that simvastatin slows brain atrophy in patients with secondary multiple sclerosis.
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[View Study](#)

FDA Continues to Defend Zohydro Despite Lawmakers Disapproval

The FDA chief defends Zohydro, while lawmakers continue to introduce bills that will force the FDA to withdraw the drug and prevent approval of similar drugs that are not tamper resistant.
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Low-Range Prehypertension May Predispose Patients to Stroke

A recent study demonstrated that people with low-range prehypertension are at an increased risk of stroke, although stroke is primarily associated with high-range prehypertension.
[View Abstract](#)

Nicotine Patches Yield No Better Result in Pregnant Women

New research shows that, despite adjustment of nicotine (patch) doses to suit actual dose in cigarettes, there are no benefits to pregnant women and newborn.
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Study Suggests Glucosamine Provides No Benefit for Chronic Knee Pain

A study suggests there is no structural benefit or decrease in cartilage deterioration associated with glucosamine in patients taking the supplement for 6 months.
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Pharmacy Provider Status Updates

The American Pharmacists Association announces the introduction of a bill in Congress that may grant pharmacists provider status and provide coverage for patient care services provided by pharmacists.
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Women's Health Initiative Calcium and Vitamin D Trial

A new study shows that vitamin D supplementation may help lower bad cholesterol in post-menopausal women.
[View Abstract](#)

Oxytocin and HCG Hormone Combo May Benefit Patients with Intractable Pain

Researchers have determined that simultaneous use of two natural hormones, oxytocin and Human Chorionic Gonadotropin (HCG), which are normally released in large amounts during and after childbirth, may result in decreased need of opioid analgesics and relief for intractable pain.
[View Item](#)

New York City Health Department Reports Measles Outbreak and Encourages Vaccination

The Health Department in NYC reports identification of 16 cases of measles, four cases requiring hospitalization, and urges all residents to become vaccinated with MMR vaccine.
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DEA One Step Closer to Rescheduling Hydrocodone Combination Products

A Notice of Proposed Rulemaking for rescheduling hydrocodone combination products from Schedule III to Schedule II has been published in the *Federal Register* by the DEA.
[View Item](#)

Study Shows CKD Patients with Atrial Fibrillation May Still Benefit From Warfarin Therapy

Research shows that patients with chronic kidney disease (CKD) on warfarin therapy for atrial fibrillation may be at increased risk of adverse bleeding events; however, a recent study discovered these patients benefited from warfarin therapy.
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Spiriva Respimat Reduces Severe Exacerbations in Asthma Patients

Spiriva Respimat (tiotropium) was found to improve lung function and decrease severe exacerbations in asthma patients already on maximum doses of other medications.
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Generic Plan B Available Over-the-Counter with No Age Restrictions

The FDA has lifted the 17 and older age restriction for over the counter generic Plan B (the morning-after pill).
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Exposure to Secondhand Tobacco Smoke Linked to Adverse Pregnancy Outcomes

A recent study conducted by the Women's Health Initiative has determined secondhand tobacco exposure is associated with increased risk of adverse pregnancy outcomes including miscarriage, stillbirth, and ectopic pregnancy.
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Appropriate MMR Vaccination Schedule Associated with Fewer Future Hospitalizations

Researchers have observed fewer rates of hospital admissions for other infections in children who received their measles, mumps, rubella (MMR) vaccine on schedule.
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Emergence of Polio-Like Illness in California

Cases in a recent study included children with paralysis explained by abnormal spinal cord MRI scans, and there are between 20-25 reported cases to date of this polio-like syndrome.
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Drug Approvals

FDA Approves ANDA for Atovaquone Oral Suspension

Anmeal Pharmaceuticals' atovaquone, the generic version of GlaxoSmithKline's Mepron, which is used to prevent *Pneumocystis jirovecii* pneumonia in immunocompromised patients, has received FDA approval of the abbreviated new drug application for an oral suspension.
[View Item](#)

FDA Approves Otezla for Psoriatic Arthritis

Otezla (apremilast), a phosphodiesterase-4 inhibitor, has been approved for treatment of psoriatic arthritis and is currently being studied for a possible treatment option for psoriasis and ankylosing spondylitis.
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[View Approval](#)

Impavido Receives FDA Approval in U.S.

Impavido is used to treat the three main types of leishmaniasis, a parasitic disease acquired while traveling overseas to tropical areas, and is the first FDA-approved drug for treatment of 2 specific types of leishmaniasis, cutaneous and mucosal.
[View Item](#)

FDA Approves Xartemis XR for Acute Pain Management

FDA approves new Schedule-II drug manufactured by Mallinckrodt, Xartemis XR (oxycodone and acetaminophen), for acute pain management.
[View Item](#)

Apixaban Receives FDA Approval for DVT Prophylaxis Following Hip or Knee Replacement

Apixaban (Eliquis) receives new FDA approved indication for deep vein thrombosis (DVT) prophylaxis in patients who have undergone surgery for hip or knee replacement.
[View Item](#)

Avedo Receives Approval from FDA

Avedo, a replacement therapy for testosterone, has been approved by the FDA for treatment of male hypogonadism after previously being rejected three times.
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Teva Receives Generic Approval for Evista in U.S.

Teva receives approval for generic Evista (raloxifene) and will begin shipping raloxifene 60 mg tablets within the next 30 days.
[View Item](#)

FDA Approves Once-Weekly Bydureon Pen for Type 2 Diabetes

Bydureon (exenatide) Pen is a pre-filled device used once-weekly in patients with Type 2 diabetes along with diet and exercise for improved blood glucose control.
[View Item](#)

Myalept Approved for Generalized Lipodystrophy/Leptin Deficiency

Myalept (metreleptin) for injection has been approved to treat individuals with congenital or acquired generalized lipodystrophy leading to complications of leptin deficiency such as diabetes mellitus and hypertriglyceridemia.
[View Approval](#)

Drug Approval: Northera for Neurogenic Orthostatic Hypotension

FDA approves Northera (droxidopa) for the treatment of neurogenic orthostatic hypotension.
[View Approval](#)

FDA Approves Vimizim for Treatment of Morquio A Syndrome

Vimizim (elosulfase alfa) is the first drug approved for treatment of a rare disorder in which an individual lacks the enzyme N-acetylgalactosamine-6-sulfate sulfatase (GALNS) called Morquio A Syndrome.
[View Approval](#)

Imbruvica Approved for Chronic Lymphocytic Leukemia

FDA grants accelerated approval of Imbruvica for treatment of chronic lymphocytic leukemia.
[View Approval](#)

FDA Approves Hetlioz for Non-24 Hour Sleep-wake Disorder in Blind Individuals

Hetlioz (tasimetelton), a melatonin receptor agonist, is the first drug approved for treatment of non-24 hour sleep-wake disorder in blind individuals.
[View Approval](#)

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New Guidelines

Updated Recommendations from CDC for Laboratory Diagnosis of Chlamydia and Gonorrhea

CDC provides updated recommendations for screening tests involved in the laboratory diagnosis of *C. trachomatis* and *N. gonorrhoeae* infections.
[View Recommendation](#)

New European Clinical Practice Guidelines on Hyponatremia

Europe has released new clinical practice guidelines on the diagnosis and treatment of hyponatremia.
[View Guideline](#)

New Practice Guidelines for Management of Valvular Heart Disease

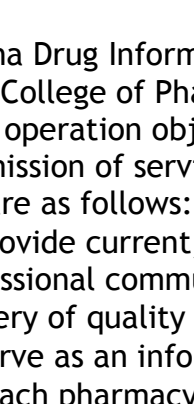
The American Heart Association and the American College of Cardiology have issued new practice guidelines for the management of patients with valvular heart disease.
[View Guideline](#)

Guideline Update: Prevention of Stroke in Nonvalvular Atrial Fibrillation

The American Academy of Neurology has issued an updated guideline on stroke prevention in patients with nonvalvular atrial fibrillation.
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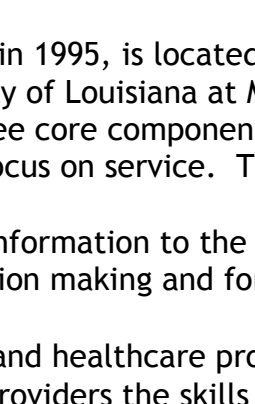
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318-342-5501

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The Louisiana Drug Information Center (DIC), which became operational in 1995, is located on the first floor of the College of Pharmacy (COP) Bienville Building of the University of Louisiana at Monroe (ULM). The operation objectives of the DIC are centered around the three core components of the University mission of service, teaching and scholarship, with a primary focus on service. These objectives are as follows:

- ◆ To provide current, comprehensive, objective and need-specific information to the healthcare professional community of the State of Louisiana for clinical decision making and for the delivery of quality patient care.
- ◆ To serve as an information resource center for faculty, students and healthcare professionals.
- ◆ To teach pharmacy students, pharmacists, and other healthcare providers the skills of efficient literature retrieval, critical evaluation of the information, and accurate communication of a response.
- ◆ To conduct research for the advancement of drug information and pharmacy practice.

The service component makes up the largest portion of the DIC operation and includes providing assistance with areas such as literature retrieval, evidence-based recommendations and off-label use of medications. We respond to drug information requests from healthcare professionals regarding the following areas:

- Adverse Drug Events
- Availability of Products
- Complimentary and Alternative Medicine
- Clinical Kinetics
- Drug Dosage and Scheduling
- Drug Identification
- Drug Interactions
- Drug Regulations/Laws
- Drug Use Evaluation Support
- Institutional Review Board Support
- Investigational/Foreign Drugs
- IV Compatibility
- Laboratory Interpretation
- Pharmacoeconomics
- Pharmacy and Therapeutics Committee Support
- Pregnancy and Lactation
- Product Compounding
- Therapeutic Drug Monitoring
- Therapeutic Uses/Drugs of Choice
- Toxicology
- Travel/Health Information

The DIC has a new phone number and provides information services exclusively to the healthcare professionals of the State of Louisiana. Additionally, this service is available to Medicaid providers through support from the Louisiana Medicaid Pharmacy Benefits Management Program.

Please contact us and let us assist you with any drug information needs at our new number for Healthcare Professionals Drug Information Service: **318-342-5501**

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For comments and suggestions please email druginfo@ulm.edu.

Disclaimer: No information source can replace clinical judgment applied to a specific case. Some of the drug therapy we write about will be outside the labeled indications for specific products. References will be provided when possible. Consult these references, product labeling, and/or give us a call if we can help with specific cases. This newsletter is supported by the University of Louisiana at Monroe College of Pharmacy and is not intended for commercial promotion.