Tanta University
College of Pharmacy
Drug Information and Control Center

Drug & Poison Information Bulletin

VOLUME1 ISSUE2 MAY 2014

FDA Clears New Formulation of Raltegravir for Infants

The US Food and Drug Administration (FDA) has approved the HIV medication ***raltegravir*** for pediatric oral suspension. The oral suspension may be used in patients as young as four weeks of age, weighing at least 3 kg to less than 20 kg.
The new oral suspension formulation will be available in the United States during the third quarter of 2014.

Source: www.medscape.com, January 09, 2014.

INSIDE THIS ISSUE:

Medical & Pharmaceutical News

Statin use reduces delirium in critically ill patients

Ongoing use of statin therapy in critically ill patients may be associated with reduced risk for dementia, and this effect may be mediated by the anti-inflammatory properties of statins.
Neuro-inflammation is believed to be a significant factor in delirium pathophysiology. Statins have a number of anti-inflammatory properties and have been the focus of potential therapies for a number of clinical conditions thought to be linked to systemic inflammation.
Delirium, one such condition, occurs in up to 65% of critically ill patients on mechanical ventilation in the United Kingdom and is a predictor of significantly worse clinical outcomes. The researchers designed a prospective cohort study of 470 consecutive intensive care unit patients who were tr t 2011 to February 2012 to find out what effect sta n patients in intensive care units who are at risk for del , and the study population included patients who ha a variety of problems, including elective emergenc d surgical reasons.

Attending nurses regularly scored levels of patient se d Agitation Sedation Scale and then assessed delirium using the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU). They also monitored levels of C-reactive protein (CRP), an established marker of systemic inflammation.
In this population of patients admitted to critical care, the researchers found that ongoing statin therapy was associated with a lower daily risk of delirium as well as a concomitant reduction in serum CRP. More specifically, they found that administration of statins the previous night was significantly associated with patients being free of delirium the following day . Patients who received statins the previous night had lower levels of CRP the following day .
These findings are the first to suggest that ongoing statin use reduces brain dysfunction as assessed using the CAM-ICU in consecutive critical care admissions. studies are needed to confirm the findings.

Source :
American Journal of Respiratory and Critical Care Medicine. Jan. 17 .2013

Medical Safety Updates

Clarithromycin and Calcium-Channel Blocker a Fatal Combination

A warning from the FDA states that serious adverse reactions have been reported in patients taking ***Clarithromycin*** concomitantly with Cytochrome P450 3A4 substrates, which includes hypotension with ***Calcium-channel blockers (CCBs***) metabolized by CYP3A4 (such as Verapamil, Amlodipine, Diltiazem).

Because ***Clarithromycin*** is an inhibitor of the CYP3A4, previous research has shown that the antibiotic can send blood concentrations of ***CCBs*** soaring by as much as 500%.

The extent of serious adverse clinical events resulting from co-prescribing drugs was evaluated by retrospective study of older adults in Ontario who were prescribed the 2 drugs together.

The study included 96,226 adults >76 years who were newly prescribed ***Clarithromycin*** and 94,083 patients who were prescribed the alternative, ***Azithromycin***, while taking a ***CCBs*** such as Amlodipine, Felodipine, Nifedipine, Diltiazem, or Verapamil.

For patients taking a ***CCBs***, the absolute risk of hospitalization for acute kidney injury was higher in taking ***Carithromycin*** than in those also taking ***Azithromycin*** (0.44% vs 0.22%; odds ratio [OR], 1.98),because ***Azithromycin*** is only a weak inhibitor of CYP34A.

Patients co-prescribed ***Clarithromycin*** also had a higher risk of hospitalization for hypotension (OR, 1.60) and all-cause mortality (OR, 1.74). A subgroup analysis showed dihydropyridines, particularly ***Nifedipine***, to be the CCBs associated with the highest risk. The risk with Nifedipine was followed by Felodipine and Amlodipine.

The results, presented here at Kidney Week 2013, were also published online November 9 in *JAMA* to coincide with their presentation.

Clarithromycin may be the top choice for an antibiotic in some cases, particularly in patients who are severely immunosuppressed, such as HIV/AIDS patients, or in the treatment of extremely drug-resistant bugs, but in such cases, it is perfectly feasible to take the patient off the calcium-channel blocker and replace it with other blood pressure medication.

Source: The American Society of Nephrology 46th Annual Meeting, November 2013

Sodium Phosphate Over-the-Counter Products: Drug Safety Communication Possible Harm from Exceeding Recommended Dose

FDA is warning that using more than one dose in 24 hours of over-the-counter (OTC) Sodium phosphate [illegible]gs to treat constipation can cause rare but serious harm to the kidneys and heart, and even death. FDA has become aw[illegible]orts of severe dehydration and changes in the levels of serum electrolytes from taking more than the recom[illegible] OTC Sodium phosphate products, resulting in serious adverse effects on organs.

OTC Sodium phosphate drug products include oral solutions taken by mouth and enemas used rectally. Availab[illegible] single-ingredient drug products, containing either Sodium biphosphate or Sodium phosphate, and as combination drug products containing both ingredients.

Recommendation: Consumers and health care professionals should always read the Drug Facts label for OTC Sodium phosphate drugs and use these products as recommended on the label, and not exceed the labeled dose. Caregivers should not give the oral products to children 5 years and younger without first discussing with a health care professional. Health care professionals should use caution when recommending an oral dose of these products for children 5 years and younger. The rectal form of these products should never be given to children younger than 2 years.

Source: www.fda.gov. January 8, 2014

Medical Safety Updates (cont.)

New FDA Boxed Warning For Rituxan And Arzerra

The U.S. Food and Drug Administration (FDA) has approved changes to the prescribing information of the immune-suppressing and anti-cancer drugs **Arzerra** (ofatumumab) and **Rituxan** (rituximab) to add new *Boxed Warning information* about the risk of reactivation of hepatitis B virus (HBV) infection.

The revised labels also will include additional recommendations for screening, monitoring, and managing patients on these drugs to decrease this risk. Both **Arzerra** and **Rituxan** are used to treat certain cancers of the blood and lymph system. **Rituxan** is also approved to treat other medical conditions, including rheumatoid arthritis. Both drugs suppress the body's immune system.

In patients with prior HBV infection, HBV reactivation may occur when the body's immune infection can cause serious liver problems, including liver failure and death. Reactivation previously had HBV infection that was clinically resolved, but who later require therapy cancer. When a treatment is given that can impair the body's immune system, the previous become an active infection.

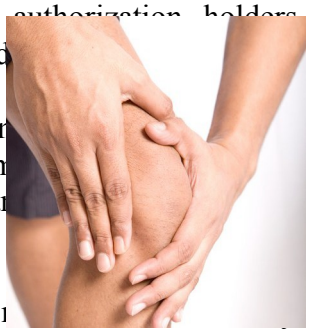
The initial HBV infection may occur without obvious signs of liver disease, and it may remain dormant in liver tissue. Therefore, screening for evidence of prior exposure is necessary to reliably assess the risk of HBV reactivation. The risk of HBV reactivation is already described in the *Warnings and Precautions* section of the labels for both drugs; however, cases continue to occur, including deaths, prompting FDA to examine this risk further for current evidence that may aid in recognition and reduction in the risk . HBV reactivation is being added to the existing *Boxed Warning* of the Rituxan label, and a new *Boxed Warning* is being created for the Arzerra label to describe the risk. The *Warnings and Precautions* section also is being revised for each drug to express new recommendations.

Source : www.fda.gov. September, 2013

Diacerein - Risk of severe diarrhea and potentially harmful effects on the liver

Pharmacovigilance Committee (PVC) based on EPVC assessment decided on 10/12/2013 the following:

"Egyptian Pharmacovigilance center (EPVC) officially requests from Marketing authorization holders (MAHs) to Submit safety documents related to Diacerein containing products in ord reviewed by EPVC"



EPVC is aware of new assessment by Pharmacovigilance Risk Assessment Comm European medicine agency (EMA) and the committee recommendation to suspend the m of Diacerein containing products in Europe because of the risk of severe diarrhea a effects on the liver.

Diacerein: known as diacetylrhein, is a drug used in the treatment of osteoa inhibiting interleukin-1.

Source : Egyptian Pharmaceutical Vigilance Center (EPVC) Volume 5, Issue 1

Drug and Therapeutic Committee (DTC)

Definition of Drug and Therapeutic Committee:

The DTC is the main body within a hospital, or group of health facilities. It is composed of actively practicing physicians, other prescribers, pharmacists, nurses, administrators, quality improvement managers, and other health care professionals and staff who participate in the medication-use process.

Why are drug and therapeutics committees needed?

Inappropriate use of medicines wastes resources and seriously undermines the quality of patient care. A drug and therapeutics committee (DTC) can significantly improve drug use and reduce costs in hospitals and other health care facilities. Medicines are often managed and used inefficiently and irrationally. This may be due to many factors:

- Poor selection of medicines, without consideration for relative efficacy, cost-effectiveness or local availability.
- Inefficient procurement practices, resulting in non-availability, inadequate quality, wastage, or use of unnecessarily expensive medicines.
- Prescribing not in accordance with standard treatment protocols.
- Poor dispensing practices resulting in medication errors, and patients' lack of knowledge about dosing schedules.
- Patients not adhering to dosing schedules and treatment advice.

Goals and objectives of the DTC:

The goal of a DTC is to ensure that patients are provided with the best possible cost-effective and quality of care through determining what medicines will be available, at what cost, and how they will bDTC is the evaluation and selection of medicines for the formulary list. Drugs should be selected on the basis of the standard treatment guidelines or protocols. Documented evidence for the efficacy, e used.

Functions of the DTC:

1-Advisory committee :

Provide advice to medical staff, nurses, administration, pharmacy and other departments and groups within the hospital. The DTC can advise on all issues, ***policies*** and ***guidelines*** concerning the selection, distribution and use of medicines.

2-Evaluating and selecting medicines for the formulary list:

The most important function of a safety, quality and cost of all drugs under consideration for inclusion in the formulary list must be examined. Periodic review is necessary because of changing costs and indications, new information on safety, and the

Drug and Therapeutic Committee (DTC)

Functions of the DTC:

3-Developing standard treatment guidelines.
4-Assessing medicine use to identify problems:
It is important for the DTC to identify the priority problems and make appropriate recommendations.
5-Managing medication errors:
Medication errors occur in all health-care settings, no matter how good the health-care staff are at prescribing, dispensing and administering medicines. Even if there is no error on the part of health-care staff, patients may take drugs incorrectly. Causes are numerous and include lack of knowledge, tiredness of staff, careless work attitudes, poor procedures lack of policies, unfamiliar dosage forms and human error. DTCs can reduce such errors by monitoring, analysing, reporting errors and implementing corrective action.
6-Conducting effective interventions to improve medicine use.
7-Managing adverse drug reactions.
8-Information dissemination and transparency:
The DTC must disseminate information about its activities, decisions and recommendations to the staff who must implement the DTC's decisions.

Organizing the committee and selecting members

A dedicated and committed **chairperson** and **secretary** are critical to the success and efficiency of a DTC. In most hospitals, a senior medical doctor, ideally well-known and respected, is appointed as the chair and the chief pharmacist as the secretary.
Members should be selected with reference to their positions and responsibilities and they should have defined terms of reference. In most hospitals, the membership includes:

- A representative clinician from each major specialty, including surgery, obstetrics and gynecology, internal medicine, pediatrics, infectious diseases, and general practice (to represent the community)
- A clinical pharmacologist, if available
- A nurse, usually the senior infection control nurse, or sometimes the matron
- A pharmacist (usually the chief or deputy chief pharmacist), or a pharmacy technician where there is no pharmacist
- An administrator, representing the hospital administration and finance department
- A clinical microbiologist, or a laboratory technician where there is no microbiologist
- A member of the hospital records department.
- Other members may include a drug information specialist, quality assurance specialist or consumer group representative.

New FDA Approval

ReSure Sealant Gel Approved for Eye Surgery

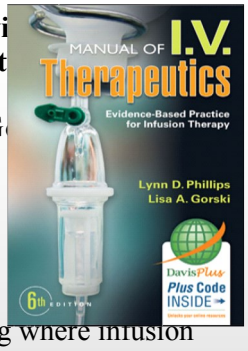
A sealant gel to prevent fluid leakage after cataract surgery has been approved by the U.S. Food and Drug Administration.

While gels such as ReSure have been approved to seal small incisions in other parts of the body, this is the first such approval for the eye, the agency said in a news release. Prior to today's approval, stitches were the only option for closing a leaking corneal incision after cataract surgery.

The ReSure sealant is produced by Ocular Therapeutix, based in Bedford, Mass.

Source: www.drug.com. Jan.10, 2014

Manual of I.V. Therapeutics: Evi
Practice for Infusion Therapy, 6t



Author: Lynn D. Phillips, Lisa G

Publication Date: 17/2/2014

Price: about $49.95 (US)

The perfect resource for any setting where infusion therapy skills are required. Its popular, self-paced approach makes it ideal for classroom and clinical settings as it progresses from the basics to advanced techniques while incorporating theory into clinical application. An expanded focus on evidence-based practice, a more streamlined format, and new *Plus* Code Premium resources online at Davis*Plus* continue to make this the manual of choice in a rapidly advancing field.

Upcoming Conferences

- 12th Annual UC Davis Clinical Pharmacotherapy 2014 **14 Mar** 2014 to **16 Mar** 2014, Napa.
- American Society For Clinical Pharmacology And Therapeutics 115th Annual Meeting 2014 **18 Mar** 2014 to **22 Mar** 2014, Atlanta.
- 9th International Congress on Autoimmunity 2014 **26 Mar** 2014 to **30 Mar** 2014, Nice.
- 11th Mediterranean Meeting On Hypertension And Atherosclerosis 2014 **04 Apr** 2014 to **07 Apr** 2014 ,Antalya.
- Dubai World Dermatology & Laser Conference 2014 **08 Apr** 2014 to **10 Apr** 2014 ,Dubai.
- Egyptian League Against Rheumatism 2014 **09 Apr** 2014 to **12 Apr** 2014 Cairo.

Editorial Board

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