King Saud University
College of Pharmacy
Drug and Poison
Information Center

Drug & Poison Information BULLETIN

مركز معلومات الأدوية والسموم
Drug & Poison Information Center

VOLUME32 ISSUE 2

April – June 2014

FDA approves Sivextro (tedizolid phosphate), to treat skin infections

Sivextro is approved to treat patients with acute bacterial skin and skin structure infections (ABSSSI) caused by certain susceptible bacteria, including Staphylococcus aureus (including methicillin-resistant strains (MRSA) and methicillin-susceptible strains), various Streptococcus species, and Enterococcus faecalis. Sivextro is available for intravenous and oral use

Source: U.S.FDA

In this issue .. ..

Medical News

Corona virus (MERS-CoV) Middle East Respiratory Syndrome - Corona virus

Coronaviruses are a family of viruses that can cause colds, and in some cases can cause severe acute respiratory syndrome (SARS). Most cases of the virus infections have common symptoms including high temperatures, body aches, sore throat, running nose and cough. In most circumstances, these symptoms last for days and then disappear.

The Ministry of Health (MOH) is working alongside with the World Health Organization (WHO) to discover more about the pathology of the virus.

Since its emergence, Coronavirus cases have been detected in a number of regions across the Kingdom. The Ministry of Health's website is being updated on a daily basis with those numbers. It is important to keep things in perspective: the total number of cases of infection in the kingdom from the month of Shawwal 1433H (September 2012) and as of 6 May 2014 are 449 cases, with 121 fatalities. The number of verified cases of infection on May 6, 2014 was 78 active case . There is an assumption by the medicalcommunity that this strain of Coronavirus is transmitted similarly to alternate strains which includes: Direct transmission through droplets expelled during coughs and sneezes. Indirect transmission through touching surfaces and devices contaminated with the virus, and then touching the mouth, nose or eyes. Direct contact with patients or infected animals or animal products.

The Ministry of Health (MOH) is working closely with a number of international organizations, including the World Health Organization (WHO), to determine how thevirus is spread, in humans and animals. According to the discovered cases so far, the symptoms may include the following: Fever and cough, Shortness of breath , Congestion in the nose and throatDiarrhea.In advanced cases, the patient can have very serious complications, which may lead to death, such as: severe pneumonia.

Source: www.moh.gov.sa

CORONA VIRUS

Middle East Respiratory Syndrome- Coronavirus (MERS-CoV)

According to the recommendations of the specialized scientists who attended the International Medical Meeting in Riyadh

HOW CORONA VIRUS DOES TRANSMIT BETWEEN PEOPLE?

MERS-CoV transmits like other Corona viruses and Flu, which transmits through:

1. Direct contact with infected patients.
2. Droplets during the patient›s coughing or sneezing.
3. Contact with patient›s tools then touching the nose, mouth or eyes directly.
4. Possibly Transmitted by infected Camels.

WHAT ARE THE SIGNS AND SYMPTOMS OF CORONA VIRUS INFECTION?

- Cough
- Fever
- Congestion in the nose and throat
- Shortness of breath
- In some cases: Diarrhea

WHAT ARE THE POSSIBLE PROTECTION MEASURES FOR CORONA VIRUS?

1. Wash your hands well and continually with water and soap, or other hand disinfectants, especially after coughing, sneezing, using toilets, before handling/preparing food, and after contact with patients or their personal tools.
2. Avoid contact with patients and their personal tools, and use face-masks only if you're sick or visiting sick patients.
3. Avoid touching your eyes and/or nose as much as possible.
4. Use a tissue when coughing or sneezing, then get rid of it in a waste basket. After that, wash your hands carefully. If there is no tissue, it is preferred to cough or sneeze into your upper sleeve or elbow, not your hands.
5. Maintain good hygiene habits in general.
6. Wash vegetables and fruits thoroughly before eating them.
7. Maintain other healthy habits such as balanced diet, physical activity, as well as getting enough sleep; this will strengthen immunity.

Do you have any inquiry . . ?

/MOHPortal
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المريض أولاً Patient First
www.moh.gov.sa/coronanew

World Health Organization

وزارة الصحة
Ministry of Health

Smokers with BRCA2 gene mutation 'have increased lung cancer risk'

It is well known that mutations in the BRCA genes increase the risk of female breast and ovarian cancers. But for the first time, researchers from The Institute of Cancer Research in the UK have discovered a link between smokers with a BRCA2 gene mutation and increased risk of lung cancer. According to the American Cancer Society, approximately 224,201 Americans will receive a lung cancer diagnosis this year. It is common knowledge that smoking is the leading risk factor for lung cancer, causing at least 80% of deaths from the disease.

But the researchers of this latest study, led by Richard Houlston, professor of molecular population and genetics at The Institute of Cancer Research (ICR), say past studies have indicated that genetic factors may also increase lung cancer risk. To investigate further, the research team compared the DNA of 11,348 European individuals who had lung cancer with the DNA of 15,861 Europeans who were free of the disease.

Their findings, recently published in the journal *Nature Genetics***, revealed that smokers who had mutations in the BRCA2 gene had a 25% chance of developing lung cancer during their lifetime. Smokers in general have around a 13-15% chance of lung cancer, so the study results show that a BRCA2 gene mutation can increase lung cancer risk even further.**

Smokers with a BRCA2 gene mutation had a 25% chance of developing lung cancer in their lifetime, according to new research.

The team found that this association was most prominent among study participants who had squamous cell lung cancer - the most common subtype of the disease. In addition, they discovered that individuals with this subtype had a mutation in another gene, called CHEK2. This gene usually stops cell division following DNA damage

PARP inhibitors 'possible treatment'

According to the researchers, the study results indicate that patients with squamous cell lung cancer may benefit from drugs that are already known to be effective in cancer patients with BRCA mutations.
For example, the investigators note that in clinical trials, poly ADP ribose polymerase (PARP) inhibitors have proved successful in breast and ovarian cancer patients with BRCA mutations. But the researchers point out that as yet, it is unclear as to whether such drugs would work for lung cancer patients.Commenting on the team's findings, Prof. Houlston says: "Our study showed that mutations to two genes, BRCA2 and CHEK2, have a very large effect on lung cancer risk in the context of smoking. Mutated BRCA2 in particular seems to increase risk by around 1.8 times.We know that the single biggest thing we can do to reduce death rates is to persuade people not to smoke, and our new findings make plain that this is even more critical in people with an underlying genetic risk."

Earlier this year, *Medical News Today* reported on a study that revealed even third hand smoke - exposure to the toxic compounds of tobacco smoke from dust or surfaces in a room where a person has smoked previously - may damage DNA and increase cancer risk. A more recent study, conducted by researchers from the University of Manchester in the UK, found that smoking and passive

Source: Honor Whiteman

FDA Approves Omidria for Use in Cataract and Other Intraocular Lens Replacement Procedures

(June 2, 2014)

U.S. Food and Drug Administration (FDA) has approved Omidria (phenylephrine and ketorolac injection) 1%/0.3% for use during cataract surgery or intraocular lens replacement (ILR) to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative pain.

Omidria, the first commercial product from Omeros' PharmacoSurgery® platform, is a proprietary combination of a mydriatic (pupil-dilating) agent and an anti-inflammatory agent that is added to irrigation solution standardly used during cataract surgery and other ILR procedures (e.g., refractive lens exchange), collectively the most common surgical procedures performed in the U.S. at nearly four million annually. Omidria is the only FDA-approved product for intraocular use that prevents intraoperative miosis and reduces postoperative pain, providing consistent and predictable management of both of these ILR-related problems for ophthalmic surgeons and their patients.

Systemic exposure of phenylephrine may cause elevations in blood pressure. In clinical trials, the most common reported adverse reactions at two to 24 percent are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation. Omidria must be diluted prior to use. Omidria is not approved for use in children.

Source: Source: U.S.FDA

FDA Approves Eloctate - first Ant hemophilic Factor, Fc Fusion Protein for Patients with Hemophilia A

(June 6, 2014)

The U.S. Food and Drug Administration today approved Eloctate, Antihemophilic Factor (Recombinant), Fc fusion protein, for use in adults and children who have Hemophilia A. Eloctate is the first Hemophilia A treatment designed to require less frequent injections when used to prevent or reduce the frequency of bleeding.

Eloctate is approved to help control and prevent bleeding episodes, manage bleeding during surgical procedures, and prevent or reduce the frequency of bleeding episodes (prophylaxis). Eloctate consists of the Coagulation Factor VIII molecule (historically known as Antihemophilic Factor) linked to a protein fragment, Fc, which is found in antibodies. This makes the product last longer in the patient’s blood.

The safety and efficacy of Eloctate were evaluated in a clinical trial of 164 patients that compared the prophylactic treatment regimen to on-demand therapy. The trial demonstrated that Eloctate was effective in the treatment of bleeding episodes, in preventing or reducing bleeding and in the control of bleeding during and after surgical procedures. No safety concerns were identified in the trial.

Eloctate received orphan-drug designation for this use by the FDA because it is intended for treatment of a rare disease or condition.

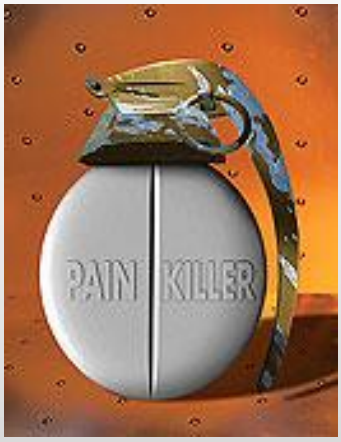
Source: Source: U.S.FDA

Use Prescription Painkillers Safely

Powerful prescription painkillers known as opioids are often involved in accidental overdoses, so experts offer tips on how to take these highly addictive medications safely."Prescription painkiller misuse is a growing epidemic. However, most people who abuse these drugs are struggling with an addiction they never intended to have," said John Ulczycki, vice president of strategic initiatives at the National Safety Council. "This National Safety Month, we hope to educate Americans on proper use so they can relieve pain without the tragic consequences of drug dependence or death."Dr. Don Teater, a medical advisor at the National Safety Council provided the following five tips to help ensure the safe use of prescription painkillers:

Consider other options. Talk to your doctor about other medications that may be more effective in controlling your pain. In most cases, Teater noted, over-the-counter nonsteroidal anti-inflammatory medications (NSAID), such as ibuprofen or naproxen, are better options for pain management. They also have fewer side effects. NSAIDs can also be combined with acetaminophen to make them more effective.**Limit usage**. Prescription painkillers should be taken for the shortest time possible. If your doctor recommends taking one of these drugs for pain management, request a two- to three-day prescription instead of a seven- to 10-day supply.

Consider side effects. While taking prescription painkillers you may not be able to drive or operate machinery safely. Your judgment may also be affected. Be aware of how these drugs affect your thinking and your coordination.



Source:www.sciencedaily.com/releases/2014/06/140602150724.htm>.

Sleep Apnea May Raise Risk of Diabetes, Research Suggests

A study of more than 8,600 people suffering from sleep apnea suggests a possible increased risk for developing diabetes, Canadian researchers report. They noted that sleep apnea results in less oxygen reaching cells in the body, less sleep and an increased heart rate, all of which are associated with a biological link to diabetes. They controlled for body-mass index [a measure of weight and height that defines obesity], and severe sleep apnea was found to be independently associated with diabetes,", however, that this was an observational study, and cannot prove that sleep apnea causes diabetes. "Author is not able to investigate causality, just an association," she explained. The, director of the Behavioral Sleep Medicine Program and the Sleep-Wake Disorders Center at Montefiore Medical Center in New York City, said, "I definitely think that this is an important study highlighting the need for more sleep apnea awareness, screening and treatment.""Given the large sample size, it further places emphasis on sleep apnea as a predictor of diabetes, and hopefully with earlier intervention, it can greatly impact the health costs for diabetes management as well as improve the outcomes for many patients," she said. For the study, author collected data on 8,678 adults who were diagnosed with sleep apnea between 1994 and 2010 and didn't have diabetes. The participants were followed through May 2011. During that time 1,017 (11.7 percent) of the patients developed diabetes. The researchers found that those with the most severe sleep apnea had a 30 percent increased risk of developing diabetes compared to those with the least severe sleep apnea. Patients suffering from mild to moderate sleep apnea had a 23 percent higher risk of developing diabetes. Sleep apnea results in poor quality of sleep, making sufferers tired during the day, and are the leading cause of daytime sleepiness, according to the U.S. National Heart, Lung, and Blood Institute.

Source: MedicineNet.com

Antidepressant use during pregnancy may lead to childhood obesity, diabetes

Women who take antidepressants during pregnancy may be unknowingly predisposing their infants to type 2 diabetes and obesity later in life, according to new research from McMaster University.

The study finds a correlation between the use of the medication fluoxetine during pregnancy and an increased risk of obesity and diabetes in children. Currently, up to 20 per cent of woman in the United States and approximately seven per cent of Canadian women are prescribed an antidepressant during pregnancy.

"Obesity and Type 2 diabetes in children is on the rise and there is the argument that it is related to lifestyle and availability of high calorie foods and reduced physical activity, but the study has found that maternal antidepressant use may also be a contributing factor to the obesity and diabetes epidemic," said the study's senior investigator Alison Holloway, associate professor of obstetrics and gynecology at McMaster University.

Previous studies have found that pregnant women are particularly vulnerable to depression and it is estimated that up to one in five pregnant women have symptoms of depression during pregnancy. "While it is known that these drugs can increase the risk of obesity in adults, it is unknown whether a woman's antidepressant use during pregnancy increases the risk of metabolic disturbances in her children," Holloway says, adding the goal of their project was to determine whether maternal exposure to a commonly used antidepressant is related to the development of fatty liver, an outcome commonly seen with obesity, in the offspring.

"studies have demonstrated for the first time in an animal model that maternal use of a class of antidepressants called selective serotonin reuptake inhibitors, or SSRIs, resulted in increased fat accumulation and inflammation in the liver of the adult offspring, raising new concerns about the long-term metabolic complications in children born to women who take SSRI antidepressants during pregnancy," says PhD student Nicole De Long, who presented this research on June 22nd at the joint meeting of the International Society of Endocrinology and The Endocrine Society. Their study does not suggest women should avoid taking antidepressants during pregnancy, only that there may be risks associated with antidepressants that haven't been previously identified, Holloway says. "The benefit of the study is it may help in the identification of a high-risk group of children who may require specific interventions to prevent obesity and type 2 diabetes later in life," she says.

The next stage of their research will be to understand the mechanistic pathways behind why these drugs pose a risk. "If we can understand how the antidepressant causes adverse metabolic outcomes in the offspring than we can design therapeutic strategies to prevent the damage while allowing women who require these drugs to be treated but reduce the potential harm to the offspring?"

Source:

"Antidepressant use during pregnancy may lead to childhood obesity, diabetes." ScienceDaily. ScienceDaily, 21 June 2014. <www.sciencedaily.com/releases/2014/06/140621213019.htm>.

تحذير من استخدام المستحضرات المحتوية على الايزوتريتينوين (Isotretinoin) دون وصفة طبية ودون استلام المواد الإرشادية الخاصة لمستخدمي الدواء

14/07/1435

تود الهيئة العامة للغذاء والدواء أن توضح للمرضى والممارسين الصحيين أنها قد دشنت برنامجاً لتقليل فرص حدوث تشوهات خلقية للأجنة قد تنتج جراء استخدام الأدوية المحتوية على مادة الايزوتريتينوين (Isotretinoin) المستخدمة لعلاج حب الشباب قبل وأثناءالحمل ويشمل هذا البرنامج :

*توزيع دليل إرشادي لكافة مستخدمي الدواء.

*نموذج للموافقة قبل استخدام الدواء للتأكد من معرفة المريض بتبعات استخدامه قبل وأثناء الحمل.

*ورسائل توعوية للممارسين الصحيين حول هذا البرنامج .

ويجب على الصيدلي المختص تسليم هذه الملفات لكافة مستخدمي هذا المستحضر ، ويمكن الحصول على النسخ المعتمدة من خلال الموقع الإلكتروني للهيئة.

وتجدر الإشارة إلى وجود ثلاثة أدوية مسجلة ومسموح بتسويقها في المملكة تحتوي مادة الايزوتريتينوين بالأسماء التجارية التالية: (ROACCUTANE),(CURACNE),(XERACTAN) ،

وحيث أن من شروط استخدام هذا المستحضر التأكد التام من عدم حصول الحمل قبل وبعد البدء في استخدامه، فإن الهيئة تشدد على ضرورة التقيد بالإرشادات الخاصة باستخدامه، ومنها ضرورة استخدام طريقتين مختلفتين لمنع الحمل عند النساء قبل شهر من بدء العلاج، وطوال فترة العلاج، ولمدة خمسة أسابيع بعد انتهاء فترة العلاج .

وتنصح الهيئة المرضى بالامتناع عن استخدام هذه المستحضرات بدون وصفة طبية وبدون استلام هذه المواد الإرشادية.

وتحث الهيئة المستهلك بإبلاغ المركز الوطني للتيقظ والسلامة الدوائية عند حدوث أي أعراض جانبية للأدوية .

"الغذاء والدواء" تحذر: "فيكتوزا" لا يستخدم إلا بوصفة، ومخصص فقط للنوع الثاني من مرض السكري

10/08/1435

أكدت الهيئة العامة للغذاء والدواء السعودية أن مستحضر (فيكتوزا) (VICTOZA)

وإسمه العلمي (LIRAGLUTIDE) مسجل في الهيئة العامة للغذاء والدواء برقم (59-100-11)

وذلك منذ عام 1432هـ ،كما تم فسح عدد من الشحنات الخاصة بالمستحضر

في المملكة "وبالتالي فإنه متوفر على عكس ما ذكر في وسائل إعلام مختلفة ".

وأضافت، بأن "مستحضر (فيكتوزا) يستخدم فقط للنوع الثاني من مرض السكري،فضلاً عن أنه لا يستخدم كعلاج أولي

للمريض (First-line therapy) كما هو موضح في الرسالة الموجهة للممارسين الصحيين، والصادرة من الشركة المصنعة"،

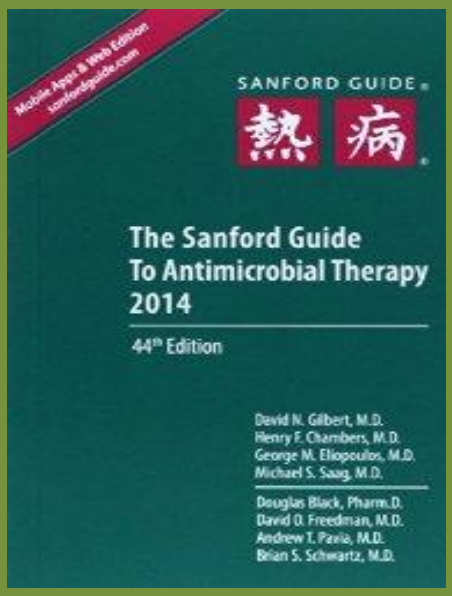
وتؤكد على أن صرفه للمرضى يقتصر على استشاري الغدد الصماء بالمستشفيات فقط، نظراً لاحتمال ارتباطه بعدد من الأعراض الجانبية، ومنها إلتهاب حاد للبنكرياس وكذلك سرطان الخلايا (سي) بالغدة الدرقية.

وأضافت: "كان من الواجب (مهنيا) على الشركة الصانعة، الحديث عن خطط خفض مخاطر المستحضر والتي تمت الموافقة عليها من قبل الهيئة العامة للغذاء والدواء ومنها توزيع دليل إرشادي لاستخدام المستحضر على المرضى".

المصدر: الهيئة العامة للغذاء والدواء

Scientific Books: New Release

Sanford Guide to Antimicrobial Therapy 2014 (Pocket Edition) (Guide to Antimicrobial Therapy by David N., Ed. Gilbert



The 44th edition of the leading reference on treatment of infectious diseases and anti-infective drug information. Available in print in pocket size, spiral bound and large library editions

new material and areas of significant change in this 44th edition include *Inhalation antibiotics* An area of therapeutics increasingly important for treatment of cystic fibrosis and infection from highly resistant aerobic gram-negative bacilli. *Photosensitivity* has been reworked for better practical use, *Surgical prophylaxis, HCV treatment* , *Influenza* has been extensively updated to reflect the 2014 flu season and treatment options. Dosing of polymyxins continue to evolve as new data become available.

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Upcoming Conferences

- 8th July 2014
  Pediatrics Drug Development,
  London, United Kingdom
- 8th - 10th July 2014
  International Conference on Geriatrics & Gerontology Chicago North Shore, United States
- 10th July 2014
  Emergence of Antimicrobial Resistance in 2014 and How To Stop It , London, United Kingdom
- 29th July 2014 , FDA Conference: FDA Device Software Regulation Fremont,C A, United States
- 4th - 6th August 2014
  4th International Conference on Proteomics and Bioinformatics Chicago, USA

Editorial Board

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ISSN: 1319 – 43021319 – 4302 :ردمد