King Saud University
College of Pharmacy
Drug and Poison
Information Center

Drug & Poison Information BULLETIN

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Low-dose aspirin use linked to improved colon cancer survival

Aspirin is a medication most commonly used to treat mild to moderate pain and inflammation. But new research suggests that patients who have been diagnosed with colon cancer may have better survival by taking low doses of the drug. In their study, the research team says aspirin use following colon cancer diagnosis was linked with overall improved survival of colon cancer, compared with non-use of aspirin, particularly among patients whose tumors expressed HLA class I antigens ***SOURCE : JAMA Internal Medicine.***

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Medical News

Acetaminophen Prescription Combination Drug Products with more than 325 mg: FDA Statement - Recommendation to Discontinue Prescribing and Dispensing

AUDIENCE: Consumer, Dentistry, Emergency Medicine, Internal Medicine, Pharmacy, Pain Management, Surgery

ISSUE: FDA is recommending health care professionals discontinue prescribing and dispensing prescription combination drug products that contain more than 325 milligrams (mg) of acetaminophen per tablet, capsule or other dosage unit. There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death. Cases of severe liver injury with acetaminophen have occurred in patients who: took more than the prescribed dose of an acetaminophen-containing product in a24-hourperiod; took more than one acetaminophen-containing product at the same time; or drank alcohol while taking acetaminophen products.

BACKGROUND: In January FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage which can result from taking too much acetaminophen. This category of prescription drugs combines acetaminophen with another ingredient intended to treat pain (most often an opioid), and these products are commonly prescribed to consumers for pain, such as pain from acute injuries, post-operative pain, or pain following dental procedures. Acetaminophen is also widely used as an over-the-counter (OTC) pain and fever medication, and is often combined with other ingredients, such as cough and cold ingredients.

FDA will address OTC acetaminophen products in another regulatory action. Many consumers are often unaware that many products (both prescription and OTC) contain acetaminophen, making it easy to accidentally take too much.

More than half of manufacturers have voluntarily complied with the FDA request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

RECOMMENDATION: FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that they contact the prescriber to discuss a product with a lower dose of acetaminophen. A two tablet or two capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product. Health care providers and pharmacists who have further questions are encouraged to contact the Division of Drug Information at 888.INFO.FDA (888-463-6332) or druginfo@fda.hhs.gov. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's Med Watch Safety Information and Adverse Event Reporting Program:

Source: U.S.Food & Drug Administration

Study Estimates Proportion of Adults Affected by New Blood Pressure Guideline

Bottom Line:

Applying the updated 2014 blood pressure (BP) guideline to the U.S. population suggests that nearly 6 million adults are no longer classified as needing hypertension medication, and that an estimated 13.5 million adults would now be considered as having achieved goal blood pressure, primarily older adults, according to a *JAMA* study released online to coincide with the 2014 American College of Cardiology Scientific Sessions.

Full Study:

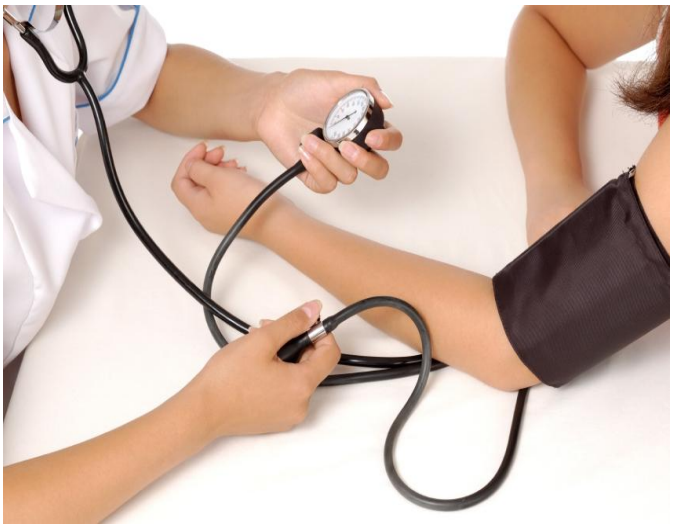
Ann Marie Navar-Boggan, M.D., Ph.D., of Duke University Medical Center, Durham, N.C., and colleagues quantified the proportion of adults potentially affected by the updated 2014 recommendations, compared to the previous guideline, issued nearly 10 years ago (Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure [JNC 7]). The researchers used data from the National Health and Nutrition Examination Survey (NHANES) between 2005 and 2010 (n = 16,372), and evaluated hypertension control and treatment recommendations for U.S. adults. The new guideline proposed less restrictive BP targets for adults 60 years of age or older and for those with diabetes and chronic kidney disease. The authors estimate that the proportion of younger adults (18-59 years) in the U.S. considered to have treatment-eligible hypertension would be decreased from 20.3 percent under JNC 7 to 19.2 percent under the 2014 BP guideline and from 68.9 percent to 61.2 percent among older adults (≥ 60 years).

Medical News (cont..)

Extrapolating these numbers to the population represented by this NHANES sample (U.S. adults in 2007) translates to a reduction in 5.8 million adults no longer classified as needing hypertension medication (70 million under JNC 7 to 64.2 million under the 2014 BP guideline). The proportion of adults with treatment-eligible hypertension who met BP goals also increased slightly for younger adults, from 41.2 percent under JNC 7 to 47.5 percent under the 2014 BP guideline, and more substantially for older adults, from 40.0 percent to 65.8 percent.

The authors estimate that 13.5 million adults not previously considered to be meeting BP targets would be considered at goal BP under the new guideline, with the majority affected age 60 years and older, and many of whom have diabetes, chronic kidney disease, and cardiovascular disease.

Overall, 1.6 percent of U.S. adults 18-59 years of age and 27.6 percent of adults age 60 years or older were receiving BP-lowering medication and meeting more stringent JNC 7 targets. These patients may be eligible for less stringent or no BP therapy with the 2014 BP guideline.



"Public health messaging should target the large number of adults in the United States with changing recommendations under new guideline to ensure that new recommendations do not result in unintended consequences in adults now with 'relabeled' BP status," the authors write. "Further research is needed to determine how this new guideline affects overall BP levels attained and to determine the related effects on cardiovascular disease outcomes."

This research was supported in part by Duke Clinical Research Institute's research funds and unrestricted grants from M. Jean de Granpre and Louis and Sylvia Vogel. Please see the article for additional information, including other authors, author contributions and affiliations, financial disclosures, etc.

Editorial: The New Cholesterol and Blood Pressure Guidelines:

Harlan M. Krumholz, M.D., S.M., of the Yale University School of Medicine, New Haven, Conn., writes in an accompanying editorial that these new guidelines, with their innovations and controversy, have established a new course. "Navigating it may be uncomfortable and will perhaps force clinicians to grapple with issues that have been ignored for too long. While it is important to advocate for health and promote healthy environments and behaviors on the broader scale, for medical decision making, it is even more important to ensure informed choice with the full participation of the person who will incur the risks and benefits of the decision. When viewed through this lens, the controversies about the guidelines become less contentious and the focus shifts to refining the evidence and producing better ways to communicate what is known for decision-making purposes. By directing attention to that message, already firmly embedded in these guidelines with their bold recommendations and deference to patient preference, they may have accomplished more than they ever envisioned."

Source: JAMA

FDA Approves Topamax for migraine prevention in adolescents

(March 28 2014) U.S. Food and Drug Administration approved Topamax (topiramate) for prevention (prophylaxis) of migraine headaches in adolescents ages 12 to 17. This is the first FDA approval of a drug for migraine prevention in this age group. The medication is taken on a daily basis to reduce the frequency of migraine headaches. Topamax was first approved by the FDA in 1996 to prevent seizures. It was approved for migraine prevention in adults in 2004.

"Migraine headaches can impact school performance, social interactions, and family life," said Eric Bastings, M.D., deputy director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research. "Adding dosing and safety information for the adolescent age group to the drug's prescribing information will help to inform health care professionals and patients in making treatment choices." About 12 percent of the U.S. population experiences migraine headaches. Migraine headaches are characterized by episodes of throbbing and pulsating pain in the head, and may occur several times per month. Other common symptoms include increased sensitivity to light, noise, and odors, as well as nausea and vomiting. Many patients experience their first migraine attack before reaching adulthood, and migraine can be just as disabling in teens as it is in adults.

The safety and effectiveness of Topamax in preventing migraine headaches in adolescents ages 12 to 17 was established in a clinical trial that enrolled 103 participants. Those treated with Topamax experienced a decrease in the frequency of migraine of approximately 72 percent compared to 44 percent in participants that took an inactive drug (placebo). The most common adverse reactions with the approved dose of Topamax (100 milligrams) were paresthesia (a burning or prickling sensation felt in the hands, arms, legs, or feet), upper respiratory infection, anorexia (loss of appetite), and abdominal pain. Topamax must be dispensed with a Medication Guide that describes important safety information about the drug. Topamax increases the risk of the development of cleft lip and/or cleft palate (oral clefts) in infants born to women who take the drug during pregnancy. The benefits and risks of Topamax should be carefully weighed before using it in women of childbearing age.

Source: Source: U.S.FDA

FDA approves Otezla to treat psoriatic arthritis

The U.S. Food and Drug Administration today approved Otezla (apremilast) to treat adults with active psoriatic arthritis (PsA). PsA is a form of arthritis that affects some people with psoriasis. Most people develop psoriasis first and are later diagnosed with PsA. Joint pain, stiffness and swelling are the main signs and symptoms of PsA. Currently approved treatments for PsA include corticosteroids, tumor necrosis factor (TNF) blockers, and an interleukin-12/interleukin-23 inhibitor. Relief of pain and inflammation and improving physical function are important treatment goals for patients with active psoriatic arthritis," said Curtis Rosebraugh, M.D., M.P.H., director of the Office of Drug Evaluation II in the FDA's Center for Drug Evaluation and Research. "Otezla provides a new treatment option for patients suffering from this disease."

The safety and effectiveness of Otezla, an inhibitor of phosphodieasterase-4 (PDE-4), were evaluated in three clinical trials involving 1,493 patients with active PsA. Patients treated with Otezla showed improvement in signs and symptoms of PsA, including tender and swollen joints and physical function, compared to placebo

Source: U.S.FDA

Obesity Prevalence Remains High in U.S.; No Significant Change in Recent Years

The prevalence of obesity remains high in the U.S., with about one-third of adults and 17 percent of children and teens obese in 2011-2012, according to a national survey study in the February 26 issue of *JAMA.*

Obesity and childhood obesity, in particular, are the focus of many preventive health efforts in the United States, including new regulations implemented by the U.S. Department of Agriculture for food packages; funding by the Centers for Disease Control and Prevention of state- and community-level interventions; and numerous reports and recommendations issued by the Institute of Medicine, the U.S. Surgeon General, and the White House, according to background information in the article. Two articles published by the authors in *JAMA* in 2012 demonstrated that the prevalence of obesity leveled off between 2003-2004 and 2009-2010, but "given the focus of public health efforts on obesity, surveillance of trends in obesity remains important." Cynthia L. Ogden, Ph.D., and colleagues from the Centers for Disease Control and Prevention, Hyattsville, M.D., examined trends

Obesity among 9,120 persons with measured weights and heights (or recumbent length) in the 2011-2012 nationally representative National Health and Nutrition Examination Survey. The prevalence of high weight for recumbent length, a standard measure of weight among infants and toddlers from birth to age 2 years, was 8.1 percent in 2011-2012, with a difference between boys (5 percent) and girls (11.4 percent). For youth (2- to 19-years of age), 31.8 percent were either overweight or obese, and 16.9 percent were obese.

Among adults, more than two-thirds (68.5 percent) were either overweight or obese, 34.9 percent were obese (body mass index [BMI] 30 or greater), and 6.4 percent were extremely obese (BMI 40 or greater).Overall, there was no change from 2003-2004 through 2011-2012 in high weight for recumbent length among infants and toddlers or in obesity in 2- to 19-year-olds or adults. The prevalence of obesity among children 2 to 5 years of age decreased from 14 percent in 2003-2004 to just over 8 percent in 2011-2012, and increased in women age 60 years and older, from 31.5 percent to more than 38 percent. The authors conclude that "obesity prevalence remains high and thus it is important to continue surveillance."

Reference:
doi:10.1001/jama.2014.732

Researchers create Smartphone device that performs blood tests

Researchers have created a Smartphone device that can perform blood tests - a creation they say could "improve the quality of life" for people undergoing treatment for the prevention of blood clots.

The formation of blood clots in the arteries and veins can increase the risk of **heart attack** and **stroke**. Individuals at high risk of blood clots are often treated with anticoagulants - drugs that thin the blood and prevent the clotting process. However, anticoagulant therapy requires patients to undergo frequent monitoring of blood flow in the hospital. Furthermore, if a person takes the wrong dosage of anticoagulants, this can cause cardiovascular problems rather than help reduce them. With this in mind, researchers from **Qloudlab** - a start-up company based in the micro engineering laboratory of the École Polytechnique Fédérale de Lausanne (EPFL) in Switzerland - have created a device that could allow patients undergoing anticoagulant therapy to self-monitor.

How does the device work?

The gadget consists of a small single-use film that is attached to the screen of a smartphone. The film is made of a micro structured plastic layer that is a few micrometers thick.

The creators say the Smartphone device (pictured) could improve quality of life for patients undergoing anticoagulant therapy.

When blood enters the film through capillary action, it can detect a molecule present in blood that initiates coagulation - the process by which blood forms clots. The phone is then able to interpret the results by analyzing interferences in the electric field on the surface of the Smartphone's screen.

This is a process similar to what happens when your finger comes into contact with the screen of a Smartphone.

The results are then sent to a specific Smartphone app, also created by Qloudlab. This data can then be sent directly to a doctor, who can assess whether a patients' treatment needs to be modified. Arther Queval, the founder of Qloudlab, says:

"Such a test will significantly improve the quality of life for people undergoing this kind of treatment."

Qloudlab has recently applied for a patent for the device, and the creators have recently received funding from **Venture Kick** that has allowed them to recruit a biochemist.

The team hopes that by the end of next year, they will have shown that the device is as reliable as a laboratory test and can progress toward commercialization. It seems that combining smart phones with self-monitoring is becoming increasingly popular. *Medical News Today* recently reported on the creation of a **Smartphone case that can measure key vital signs**, including **blood pressure**, temperature and blood oxygen.

Last year, a study from the University of California, Los Angeles, detailed the creation of a **portable device that can conduct kidney tests** and transmit the data through a Smartphone attachment.

Written by Honor Whiteman

الهيئة تحذر من مستحضر العسل الملكي (Royal Honey)

18/05/1435

تود الهيئة العامة للغذاء والدواء أن تحذر جميع المستهلكين من مستحضر العسل الملكي **(Royal Honey)** والمنتج من شركة إتيوماكس **(ETUMAX)** والذي يتم بيعه وتسويقه من قبل محلات العطارة وبعض الباعة المتجولين ومجهولين عن طريق وسائل التواصل الاجتماعي، والذي يروج له بأنه مستحضر طبيعي، وحيث أظهرت نتائج التحاليل التي تمت بالمختبرات التابعة للهيئة على احتواء مستحضر العسل الملكي **(Royal Honey)**، على مادة **(TADALAFIL)** الدوائية والتي تستخدم بموجب وصفة طبية من قبل الطبيب وتحت إشرافه، وأن الإدعاء بأنه طبيعي إدعاء مضلل وليس له أي أساس من الصحة وتوصي الهيئة جميع المستهلكين بتجنب استهلاك هذا المستحضر والتخلص مما لديهم من عينات ،علماً بأن الهيئة قامت بمخاطبة الجهات ذات العلاقة لاتخاذ الإجراءات النظامية اللازمة لسحب هذا المستحضر من الأسواق.

الهيئة تحذر من الإدعاءات الطبية "لمنقوع عشبة باما" والمنتج من شركة Nancy city Aofula pharmaceutical co.ltd

23/05/1435

تود الهيئة العامة للغذاء والدواء أن تنبه جميع المستهلكين عن وجود مستحضر (منقوع عشبة باما) العشبي والمنتج من شركة **(Nancy city Aofula pharmaceutical co.ltd)** ، والذي يحل بالماء وينقع به الأرجل، إذ يتم بيعه والترويج له في بعض القنوات الفضائية ووسائل التواصل الاجتماعي والمواقع الالكترونية على الشبكة العنكبوتية كمزيل للأرق وألم المفاصل وألم الطمث والإرهاق والصداع والإمساك والعديد من الادعاءات الطبية، وقد اتضح أن هذه الإدعاءات مضللة وليس لها أي أساس من الصحة، وإنما يستخدم فقط لتدليك الأرجل ولا يختلف في تأثيره عن أملاح البحر المستخدمة في التدليك .

كما نود أيضاً التنبيه على جميع المستهلكين أن استخدام هذا المنقوع من قبل المرأة الحامل قد يؤدي لا قدر الله إلى الإضرار بالجنين.

الهيئة تحذر من مستحضر (7Days Slimming Coffee)

26/05/1435

تود الهيئة العامة للغذاء والدواء أن تحذر جميع المستهلكين من مستحضر **(7Days Slimming Coffee)** والمنتج من شركة **(American Kangmei Bioengineering (HK) Ltd)** والذي يتم بيعه وتسويقه على هيئة أكياس تحتوي على بودرة من قبل محلات العطارة وبعض الباعة المتجولين ومجهولين عن طريق وسائل التواصل الاجتماعي ،حيث أظهرت التحاليل التي تمت بالمختبرات التابعة للهيئة على احتواء المستحضر على مادة السيبوترامين "" الدوائية وهي مادة محظورة لعدم مأمونيتها وخطرها على الصحة إذ تؤدي إلى وجود أعراض جانبية تتمثل في ارتفاع احتمالية الإصابة بأمراض القلب والشرايين والإدمان لا قدر الله . وتوصي الهيئة جميع المستهلكين بتجنّب استهلاك هذا المستحضر والتخلص مما لديهم من عينات ، علماً بأن الهيئة قامت بمخاطبة الجهات ذات العلاقة لاتخاذ الإجراءات النظامية اللازمة لسحب هذا المستحضر من الأسواق.

كما تهيب الهيئة بالمستهلكين إبلاغ المركز الوطني للتيقظ والسلامة الدوائية عند حدوث أي أعراض جانبية للأدوية.

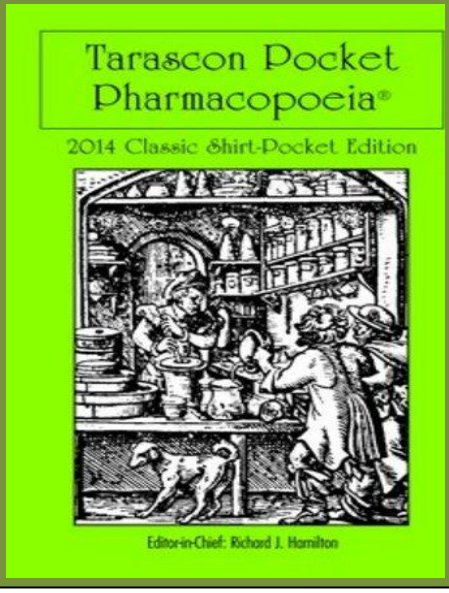
المصدر: *الهيئة العامة للغذاء والدواء*

Scientific Books: New Release

Tarascon Pocket pharmacopoeia 2014

MD,FAAEM ,FACMT,EDITOR IN CHIEF RICHARD J.HAMILTON (**Author)**

Used by prescriber around the world, including physicians, pharmacists, nurses, physician assistants, dentists, and medical transcriptionists, the Tarascon Pocket Pharmacopoeia® 2014 Classic Shirt-Pocket Edition continues its tradition as the leading portable drug reference packed with vital drug information to help clinicians make better decisions at the point of care. The Tarascon Pocket Pharmacopoeia® 2014 Classic Shirt-Pocket Edition, now updated with over 100 new drugs, details FDA approved drug dosing, available trade and generic formulations, metabolism, safety in pregnancy and lactation, relative drug pricing information, Canadian trade names, and an herbal & alternative therapies section. Multiple tables supplement the drug content, including opioid equivalency, emergency drug infusions, cardiac dysrhythmia protocols, pediatric drug dosing, and much more



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Upcoming Conferences

- **8th - 9th April 2014**
  Clinical Trial Performance Metrics LONDON UNITED KINGDOM
- 8th - 9th April 2014
  Clinical Evaluations & Investigations for Medical Devices, Hilton Dublin in Dublin, Leinster, Ireland
- 24th - 25th April 2014
  Regulatory Affairs in the USA (FDA) for Drugs and Biologics, Chicago, USA
- 5th - 8th May 2014
  Annual International Conference on Pharmaceutical Sciences, Athens, Greece
- 9th - 11th June 2014
  Pharmaceutical Packaging and Labeling Summit 2014, Switzerland

Editorial Board

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