FDA is informing healthcare professionals and patients that the drug Lamictal (lamotrigine) can cause aseptic meningitis. Lamictal is approved to treat bipolar disorder in adults, and seizures in adults and children two years and older.

FDA's review of adverse events included 40 cases of aseptic meningitis in patients treated with Lamictal. In most cases, meningitis symptoms ended after the drug was discontinued. In 15 cases, the patients experienced a rapid return of symptoms when the drug was restarted. The information about the risk of aseptic meningitis is being added to the drug's labeling and Medication Guide.

If meningitis is suspected in patients receiving Lamictal, clinicians should evaluate these patients for other causes of meningitis and initiate appropriate treatment. If no other cause is found, consider discontinuing the drug.

Patients taking Lamictal should be told to contact their healthcare professional immediately if they experience symptoms of meningitis, including headache, fever, chills, nausea, stiff neck, rash, and sensitivity to light.

Additional Information:


Preventing Bloodborne Infections When Using Fingerstick Devices

FDA and CDC are alerting healthcare professionals and patients about the risk of transmitting hepatitis B virus (HBV) and other infectious diseases when fingerstick lancing devices are used on more than one person. These devices puncture the skin to obtain small amounts of blood for testing someone's blood glucose, hemoglobin or other blood components. Some of them are designed for single use, others for multiple use. They can come packaged with point-of-care blood testing devices or sold separately.

In recent years, the FDA and CDC have noted an increase in reported HBV outbreaks associated with using multiple-use fingerstick devices on more than one person. Much of the increase has occurred in long-term care settings such as nursing homes and assisted living facilities, where residents often need someone to help monitor their blood glucose levels.

But this risk exists in any setting where fingerstick procedures are performed, including acute care facilities, as well as clinics, health fairs, shelters, detention facilities, senior centers, schools, and camps. For example, at a health fair in New Mexico earlier this year, dozens of people were potentially exposed to bloodborne pathogens when they were screened for diabetes with fingerstick devices that were being reused.

Using fingerstick devices on more than one person may not be safe for several reasons. For example, improper use or device malfunction can mean that a contaminated lancet blade might be used on more than one patient. It is also difficult to ensure that all blood has been removed from the reusable portions of the fingerstick device.
FDA and CDC recommend a number of precautions to help prevent transmission of bloodborne pathogens. Here are some of them:

- Never use fingerstick devices on more than one person.
- In situations where patients are assisted with blood glucose monitoring, use single-use disposable fingerstick devices that prevent reuse through an auto-disabling feature.
- Even when following these precautions, be sure to wash hands and change gloves between patients.

Additional Information:


Recall of INOMAX DS Drug Delivery System

The manufacturer Ikaria is recalling its INOMAX DS drug delivery system because a pressure switch in the device may fail. INOMAX delivers nitric oxide, a vasodilator, to treat term and near-term neonates with hypoxic respiratory failure associated with pulmonary hypertension.

If the pressure switch fails the nitric oxide gas could leak, possibly accompanied by a hissing sound. The leak could cause the INOMAX cylinder to empty more quickly than normally. If flow is interrupted because the cylinder is empty, or because of the time it takes to switch to a replacement, the infant could experience a worsening of oxygenation, hypotension, or an increase in pulmonary arterial pressure.

Ikaria has begun to replace the affected INOMAX DS drug delivery systems with a remediated device. In the meantime, the company says that if a pressure leak in the system is suspected, clinicians should not interrupt the delivery of INOMAX. They should verify that an adequate amount of INOMAX remains in the cylinder. They should switch to the manual back-up system using the INOblender. Clinicians who suspect a leak should also contact Ikaria Customer Care at 1-877-566-9466.

Additional Information:

FDA is notifying healthcare professionals that patients receiving the IV antibiotic Tygacil (tigecycline) to treat serious infections may have a greater risk of death than patients receiving other drugs for this purpose. Tygacil's labeling has been updated to include this information.

In the pooled clinical trials reviewed by FDA, the increased mortality risk was clearest in patients treated for hospital-acquired pneumonia, especially ventilator-associated pneumonia, but it was also seen in patients with complicated intra-abdominal and skin infections, and those with diabetic foot infections. Tygacil is not approved for hospital-acquired pneumonia or diabetic foot infections.

When treating patients with severe infections, practitioners should consider using alternatives to Tygacil. Report any adverse events involving Tygacil to the FDA MedWatch program.

Additional Information:

Suspected Counterfeit Tourniquets Pose Risk

FDA is warning emergency first responders about suspected counterfeit Combat Application Tourniquets, also known as "CAT" tourniquets, that do not work and can endanger the lives of injured people. CAT tourniquets are widely used by the military. The strap of a CAT is placed around an injured limb and then tightened with a tension rod until blood flow stops. With the suspected counterfeit tourniquets, the tension rod can break or bend before the user can apply enough force to stop blood flow, possibly endangering the victim's life.

Authentic CAT tourniquets are manufactured by Composite Resources. They have a C-A-T logo with the outline of a cat on one side of the tourniquet, along with the National Supply Number above it. The suspected counterfeit tourniquets look very similar to the authentic ones, but may have subtle differences in stitching, how the logo is printed, and how the plastic parts are molded.

FDA recommends that people use only CAT tourniquets manufactured by Composite Resources and sold by one of the following authorized distributors:

- North American Rescue LLC
- Cardinal Health
- Owens & Minor
- American Purchasing Services
- Phoenix Textile Corporation

Those who have suspected counterfeit CAT tourniquets should replace them as soon as possible with the authentic devices. If a tourniquet fails, it can fail to save a life.

FDA and the Department of Defense are continuing to investigate this issue. Report any suspected counterfeits to FDA's Office of Criminal Investigations at (240) 276-9407.

Additional Information:

stitching, how the logo is printed, and how the plastic parts are molded.

Medical Errors from Misreading Letters and Numbers

An article by the Institute for Safe Medication Practices (ISMP) reminds healthcare practitioners how dangerous it can be to misread the letters and numbers on prescriptions, drug orders and medical records. Unfortunately, these mistakes are easy to make because some of the alphanumerical symbols we use look so similar.

Research has shown that more than 50 percent of letter-number errors come from just four basic mixups: between the letter "l" and the number "1," between the letter "O" and the number "0," between the letter "Z" and the number "2," and between the numbers "1" and "7." These mixups are most likely to occur when the information contains both letters and numbers—such as in most medication orders.

In one case, a nurse misread an order for 2 mg of Amaryl as 12 mg, because the lower-case "l" at the end of "Amaryl," which was written too close to the dosage, looked like it was the number "1." In another example, a pharmacist read the word "Iodine" instead of "Lodine" because the upper case "L" in Lodine looked like an upper-case "I."

ISMP notes that cursive writing is more likely to be misread than block printing. But they also point out that it's not just handwritten information that can be misread. Even typed or computer-generated physician orders can lead to confusion, because typing the letters and numbers cannot eliminate the similarity between symbols like "l" and "1," or "O" and "0." Another problem that can lead to errors with typed orders is improper spacing between the letters and numbers. For example, even a clearly typed prescription for 25 mcg of Levoxyl could be read as 125 mcg if there is no space between the final letter in the drug name and the first number in the dosage.

ISMP recommends several ways to prevent these kinds of mixups.

• Use block printing rather than cursive writing on handwritten orders. This takes a little more time, but it can
help prevent serious errors.

- Use European-style differentiation to clearly distinguish between confusing symbols. For example, write the number "0" with a slash through it to distinguish it from the letter "O," write the number "7" with a bar through it to distinguish it from the number "1," and write the letter "Z" with a bar through it to distinguish it from the number "2."

- Be sure to allow adequate space between the drug name and the dose, both in handwritten orders and in electronic formats, including medication labels and shelf labels.

- Finally, when reading an order, make sure the dose you are viewing is within the recommended dosage range for that drug. If the dose does not seem to make sense, clarify with the prescriber.

The full ISMP article includes a list of more than 20 commonly confused letters and numbers.

**Additional Information:**


http://www.ismp.org/Newsletters/acutecare/articles/20090702.asp

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**What’s New for the 2010-2011 Influenza Vaccine**

With the influenza season upon us, the CDC is recommending that everyone aged 6 months and older get vaccinated to protect themselves and others. During the last influenza season, people needed one vaccine to protect against seasonal influenza, and another one for the 2009 H1N1 influenza. But this season's vaccine contains the 2009 H1N1 strain, along with two other strains that are predicted to cause influenza, so there is no need to get two different vaccines. As in earlier years, both inactivated and live attenuated vaccines are available.

There is now a vaccine that is specifically indicated for people 65 and older, called Fluzone High-Dose. People in this age group have the highest risk for seasonal influenza complications because people's immune systems weaken as they grow older. The new vaccine contains a higher dose of influenza virus hemagglutinin, which is intended to induce a stronger immune response and better protect the elderly against seasonal influenza.

People who are hypersensitive to egg proteins or who have had life-threatening reactions after previous influenza vaccinations should not receive the vaccine.

**Additional Information:**


http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094045.htm
Accidental Exposure of Children and Pets to Evamist

FDA is warning people about harmful effects in children and pets if they unintentionally come in contact with Evamist (estradiol transdermal spray), a topical hormone treatment used to relieve hot flashes in post-menopausal women. This can lead to premature puberty in girls and breast enlargement in boys. Similar effects have been observed in exposed pets.

Evamist contains estradiol, an estrogen hormone. Women use Evamist by spraying it on the inside of their forearms. Children can be exposed to the drug if they come in direct contact with the woman's skin where
the spray was applied. Pets can be exposed to Evamist in the same way.

If you use Evamist, do not allow children to contact the skin where the drug was sprayed. If contact with children cannot be avoided, wear long sleeves to cover the application site. If a child comes in direct contact with the area that was sprayed, wash the child's skin with soap and water as soon as possible.

Contact the child's healthcare provider if he or she shows any of these signs or symptoms: nipple tenderness or breast tenderness or swelling in girls, or breast enlargement in boys. Be sure to tell the health professional that the child may have been exposed to Evamist.

If you have pets, do not allow them to lick or touch the arm where the Evamist was sprayed. Contact your veterinarian if your pet shows signs of nipple or vulvar enlargement, or any other signs of illness.

**Additional Information:**