Indiana State Department of Health

LONG TERM CARE NEWSLETTER

ISDH Long Term Care
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Health Alerts

CDC Guidance on the Use of Influenza Antiviral Agents and Rapid Influenza Diagnostic Tests During the 2010-2011 Influenza Season

From the Indiana Health Alert Network
1/14/2011

Summary

As influenza activity increases in the United States, clinicians are urged to consult CDC guidance on the use of influenza antiviral agents and rapid influenza diagnostic tests this season. Updated recommendations on the use of antiviral medications will be published in an upcoming Morbidity and Mortality Weekly Report (MMWR), but an interim version of the recommendations is currently available on CDC's website at http://www.cdc.gov/flu/professionals/antivirals/index.htm. The updated guidance for health care professionals on the use of rapid influenza diagnostic tests is available at http://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm. For the most recent summary of influenza activity in the United States, consult the CDC influenza surveillance report FluView at http://www.cdc.gov/flu/weekly/fluactivitysurv.htm.

Recommendations

Antiviral Agents Guidance:

The recommendations on the use of influenza antiviral agents contain information on treatment and chemoprophylaxis of influenza virus infection, and also provide a summary of the effectiveness and safety of antiviral medications. Highlights include recommendations for the following:

1) early empiric antiviral treatment of suspected or confirmed influenza among people with severe, complicated, or progressive illness or those hospitalized for influenza;

2) early empiric antiviral treatment of suspected or confirmed influenza among people at higher risk for influenza complications;

3) use of either oseltamivir or zanamivir for influenza A and B treatment or chemoprophylaxis, and recommendations not to use rimantadine or amantadine as influenza antiviral medications due to high levels of resistance to these medications among circulating influenza A viruses;

4) use of antiviral medications among children younger than 1 year of age;

5) use of local data on influenza virus circulation and influenza testing of respiratory specimens from patients with suspected influenza, when available, to help inform clinicians about influenza circulation; and

6) consideration of antiviral treatment for any previously healthy, non high-risk symptomatic outpatient with confirmed or suspected influenza, based upon clinical judgment, if treatment can be initiated within 48 hours of illness onset.

Rapid Influenza Diagnostic Tests Guidance:

Recommendations on the use of rapid influenza diagnostic tests are available to help guide clinical decisions and to determine if outbreaks of respiratory illness in closed settings are due to influenza virus infection. The guidance also provides information for interpreting rapid diagnostic test results. Highlights include recommendations for the following:

1) use of rapid influenza diagnostic tests when a positive result will change the clinical management of patients or change outbreak control strategies in a population, especially if the setting includes hospitalized patients or persons at high risk for influenza-associated complications;

2) avoiding the use of negative rapid test results to guide decisions regarding treating patients with influenza antiviral medications due to the suboptimal sensitivity of rapid tests;

3) evaluation of rapid diagnostic test results in the context of other available clinical and epidemiological information; and

4) consideration of further influenza laboratory testing in the following circumstances:

a. when a patient tests negative by rapid test during periods of high influenza activity;

b. when a patients tests positive by rapid test during periods of low influenza activity; or

c. when a patient has had recent close exposure to pigs, poultry, or other animals and novel influenza A virus infection is possible.

For More Information

For Information on Use of Influenza Antiviral Agents During the 2010-2011 Influenza Season go to: http://www.cdc.gov/flu/professionals/antivirals/index.htm

For Information on Use of Rapid Influenza Diagnostic Tests for the 2010-2011 Influenza Season go to: http://www.cdc.gov/flu/professionals/diagnosis/

For other inquiries, please visit www.cdc.gov/flu or call CDC's toll-free information line, 800-CDC-INFO (800-232-4636). TTY: (888) 232-6348, is available 24 hours a day, every day.

Recall Information

Morphine Sulfate Oral Solution 100 mg per 5 mL (20 mg/mL): Medication Use Error - Reports of Accidental Overdose

ISSUE: Roxane Laboratories and FDA notified healthcare professionals of serious adverse events and deaths resulting from accidental overdose of morphine sulfate oral solutions, especially when using the high potency 100 mg/5mL product. In most of these cases, morphine sulfate oral solutions ordered in milligrams (mg) were mistakenly interchanged for milliliters (mL) of the product. The approval of this product is part of FDA's unapproved drugs initiative. Prior to the recent approval, Roxane marketed a morphine sulfate oral solution with the strength expressed as 20 mg/mL, using a container label and carton labeling that had brown lettering on a white background. The newly approved product labeling and packaging feature revisions intended to reduce the risk of medication errors.

BACKGROUND: Morphine Sulfate Oral Solution 100 mg per 5 mL (20 mg/mL) is indicated for relief of moderate to severe acute and chronic pain in opioid-tolerant patients.

RECOMMENDATION: See Roxane's "Dear Healthcare Professional Letter" for a complete description and photos of labeling and product packaging changes. Changes include:

- A warning stating "ONLY FOR USE IN PATIENTS WHO ARE OPIOID TOLERANT" is displayed in a box to highlight that the morphine sulfate oral solution 100 mg per 5 mL (20 mg/mL) is indicated for use in opioid-tolerant patients only. The 100 mg per 5 mL concentration of morphine sulfate may cause fatal respiratory depression when administered to patients not previously exposed to opioids.
- The strength is presented as 100 mg per 5 mL followed by a less prominently displayed concentration of (20 mg/mL). The intent of this designation is to help differentiate this product from the 20 mg/5 mL morphine sulfate product.
- A bright yellow background is used on multiple sides of this product to differentiate the morphine sulfate oral solution 100 mg per 5 mL (20 mg/mL) from other morphine sulfate oral solutions marketed by Roxane with a white background.
- The drug name, strength and concentration are displayed in white lettering on a red background as an additional means of differentiating this product from other concentrations of morphine sulfate oral solutions.
- A reminder is presented to the pharmacist to dispense the product to each patient with the enclosed Medication Guide.
- Both the 30 mL and 120 mL bottles of morphine sulfate 100 mg per 5 mL (20 mg/mL) oral solution are packaged with a calibrated oral syringe to provide accurate dose measurements. Healthcare providers should read the instructions in the Medication Guide that describe the correct use of the oral syringe in order to help prevent medication errors from occurring.
- Healthcare providers should discuss the correct use of the oral syringe with their patients.

Triad Alcohol Prep Pads, Alcohol Swabs, and Alcohol Swabsticks: Recall Due to Potential Microbial Contamination - Sold by Cardinal Health, PSS Select, VersaPro, Boca/Ultilet, Moore Medical, Walgreens, CVS, Conzellin

ISSUE: Triad Group, a manufacturer of over-the-counter products and FDA notified healthcare professionals and patients of the recall involving all lots of alcohol prep pads, alcohol swabs, and alcohol swabsticks manufactured by Triad but sold as private labels at the consumer level. This recall has been initiated due to concerns about potential contamination of the products with Bacillus cereus. This recall involves those products marked as STERILE as well as non-sterile products. Use of contaminated alcohol prep pads, alcohol swabs, and alcohol swabsticks could lead to life-threatening infections, especially in at-risk populations, including immune suppressed and surgical patients.

BACKGROUND: Alcohol prep pads, alcohol swabs, and alcohol swabsticks are used to disinfect prior to an injection. They were distributed nationwide to retail pharmacies and are packaged in individual packets and sold in retail pharmacies in a box of 100 packets. The affected Alcohol Prep Pads, Alcohol Swabs and Alcohol Swabsticks can be identified by either "Triad Group," listed as the manufacturer, or the products are manufactured for a third party and use the names listed below in their packaging: Cardinal Health, PSS Select, VersaPro, Boca/ Ultilet, Moore Medical, Walgreens, CVS, Conzellin.

RECOMMENDATION: If a consumer has any of these types of products in their possession listing "Triad Group" as the manufacturer, they should not use the product and should return it to the place it was purchased for a full refund.

Metronidazole Tablets, 250mg: Recall - Underweight Tablets

ISSUE: Teva Pharmaceuticals and FDA notified healthcare professionals and the public of a recall of Metronidazole Tablets USP, 250mg, lot #312566, expiration date 05/2012. This product lot is being recalled due to the presence of underweight tablets. Underweight tablets may not contain the full amount of active ingredient within a single tablet, and a consumer may not receive the prescribed dose. This may cause the infection the drug was intended to treat to worsen or recur, which could be life-threatening when treating severe infections.

BACKGROUND: Metronidazole is indicated for the treatment of symptomatic and asymptomatic trichomoniasis, and treatment of asymptomatic consorts, amebiasis and a variety of anaerobic bacterial infections. The affected Metronidazole lot is packaged in 250 count bottles and was distributed nationwide

to wholesalers and retailers.

RECOMMENDATION: Consumers who have lot 312566 in their possession are instructed to cease using the product and return it to their pharmacy.

Albuterol Sulfate Inhalation Solution 0.083%, 3 mL Unit Dose Vials: Recall - Mislabeled Unit Dose Vials

ISSUE: The Ritedose Corporation is conducting a voluntary recall of 0.083% Albuterol Sulfate Inhalation Solution, 3 mL in 25, 30, and 60 unit dose vials. This product is being recalled because the 2.5 mg/3 mL single use vials are embossed with the wrong concentration of 0.5 mg/ 3 mL and therefore, represents a potential significant health hazard. Only the unit dose vials are incorrectly embossed as containing 0.5 mg/3 mL. The correct concentration of 2.5 mg/3 mL is labeled on the primary foil overwrap pouches and shelf cartons. Administration of this defective product could result in a range of potential health effects that spans from temporary and medically reversible to life threatening and death.

There is significant concern that health professionals who read the incorrect embossed concentration may upwardly adjust the volume of product used resulting in an administered amount that is 5 times the recommended dose. In the hospital setting, the vials are often not accompanied by the rest of the packaging, making it more likely that such a dosing error could occur. Significant overdosing of a patient could lead to signs and symptoms of albuterol toxicity, which includes tremors, dizziness, nervousness, headache, seizures, angina, high blood pressure, low potassium levels, and rapid heart rates up to 200 beats/minute.

BACKGROUND: This product is a prescription inhalation solution, administered via nebulization, for the treatment and maintenance of acute asthma exacerbations and exercise induced asthma in children and adults. The product is packaged as a single use unit dose vials in a protective foil overwrap packaged in a shelf carton. The following lot numbers manufactured by The Ritedose Corporation under NDC: 0591-3797-83, 0591-3797-30, and 0591-3797-60 are included in the recall: 0N81, 0N82, 0N83, 0N84, 0NE7, 0NE8, 0NE9, 0NF0, 0P12, 0P13, 0P46, 0P47, 0PF0, and 0S15. No other Albuterol formulations or products are included in this recall. This product was distributed nationwide and Puerto Rico.

RECOMMENDATION: Consumers should immediately return the affected product to the place it was obtained (i.e. doctor’s office, pharmacy, etc.). Wholesalers and retailers should return the product to the address stated in the firm Press Release.

Reports

The next issue (November/December 2010) of the Indiana Epidemiology Newsletter has been published to the ISDH Web site. You may view the newsletter by clicking on the following link or copy and paste it into your browser window: http://www.in.gov/isdh/17458.htm or click here to download the .pdf version.

Featured articles in the November/December newsletter include:

-"Enteroviral Surveillance"

-"Trends in Antimicrobial Resistance and Serotypes among Invasive *Streptococcus Pneumoniae* isolates in Indiana, 1999-2008"

-"Cervical Cancer"

-"Norovirus Outbreak at a Birthday Party"

Have a good week.

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