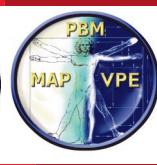




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Medication safety in seconds

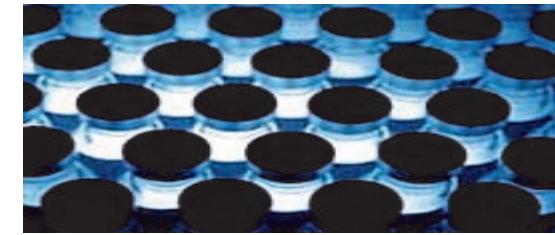
A MONTHLY PUBLICATION FROM VA MEDSAFE:
VA'S COMPREHENSIVE PHARMACOVIGILANCE CENTER

Helping to achieve safe medication use

REMINDER: HEPARIN LABELING CHANGES

The new labeling standard for **Heparin Sodium Injection USP** and **Heparin Lock Flush Solution USP** becomes official in May 2013. Both the current heparin container labels and the revised heparin container labels may be available during the transition period before and after the implementation date in May. There are several steps you can take to help ensure a smooth transition and decrease the chance of a medication error:

- Store “current” and “revised” heparin in separate areas of the pharmacy.
- Ensure stock is not mixed together in patient care areas.
- Educate ALL staff involved in procurement, storage, ordering, dispensing, and administration of heparin. Engage patient safety, providers, and nursing in your educational efforts. Consider including information in newsletters, e-mail announcements, and other forms of communication your medical center may use such as daily bulletins.
- Engage informatics staff to review quick orders, drug



menus, etc., to ensure language is consistent with new labels.

- Consider independent double checks during the dispensing and administration phases.

USP provides information regarding the new standard on their [resource page](#). Details include:

- [Heparin Labeling Change FAQ](#)
- [Webinar for Practitioners – Be Alert During Label Transitions](#)
- [Heparin Webinar Recording](#)
- [Information on USP's standards-setting activities related to Heparin](#)

Additional information can be found at:

<http://www.ajhp.org/content/70/8/650.2.full?etoc>

REFERENCES:

1. USP. Heparin Labeling Changes. <http://www.usp.org/usp-healthcare-professionals/medication-safety-labeling/heparin-labeling-changes>. Accessed 04/01/2013.
2. C Thompson. Diligence needed during transition in heparin products' labels. *American Journal of Health-System Pharmacy*. April 15, 2013. 70 (8): 650-652.



NEWS YOU CAN USE

FROM THE VA NATIONAL PBM: BULLETINS, COMMUNICATIONS, & RECALLS

- Sodium Phosphate Enema and Fatal Outcome -03/26/2013 - [National PBM Bulletin](#)
- Pregnesatide Injection Recall and Anaphylaxis - 03/04/2013 - [National PBM Communication](#)

EDITOR-IN-CHIEF | Marie Sales, Pharm.D.

VA Pharmacy Benefits Management Services [PBM] & Center for Medication Safety [VA MedSAFE]

1st Avenue—1 Block North of Cermak Road | Building 37; Room 139 | Hines, Illinois | 60141

www.pbm.va.gov

NEWS YOU CAN USE

FROM THE FOOD AND DRUG ADMINISTRATION (FDA)

MISCELLANEOUS

FDA Alerts Healthcare Providers that Drugs Distributed by Shamrock Medical Solutions May Be Mislabeled

04-11-2013

An inspection conducted by the FDA shows that drugs from Shamrock Medical Solutions Group LLC (Shamrock) may be mislabeled with drug labels that describe (1) a different drug than what was included in the container; (2) a drug with the wrong dosage strength; and (3) a drug not identified as extended release. Healthcare providers should check medical supply stocks and remove all products from Shamrock, including all drugs and dosage forms (i.e., tablets, vials, ophthalmic and otic solutions, and patches). Shamrock repackages and re-labels drugs for 91 hospitals, pharmacies and medical centers. Shamrock has received warning in the past regarding violations of current good manufacturing practice (CGMP) and distributing incorrectly labeled drugs.

Getting the most from our safety surveillance

PREVNAR 13 AND PNEUMOVAX 23

Pneumococcal 13 Valent Conjugate Vaccine (Prevnar 13) has been added to the VA Formulary with restrictions to Criteria for Use. Recently, a report documented a physician ordering Prevnar 13 for two patients who were instead administered the Pneumovax 23 vaccine. A National PBM Bulletin issued on April 10, 2013 addresses this medication error and the appropriate use of the Prevnr 13 and Pneumovax 23 vaccines according to recommendations from the Advisory Committee on Immunization Practices (ACIP).

Pneumovax 23 (polysaccharide; PPSV23) and Prevnr 13 (conjugate; PCV13) are vaccines used for the prevention of invasive pneumococcal disease. Pneumovax 23 and Prevnr 13 cover 12 overlapping serotypes, with Pneumovax 23 providing further protection against 11 additional serotypes while Prevnr 13 addresses 1 more serotype. While both Prevnr and Pneumovax are indicated for persons with immunocompromised conditions, cerebrospinal fluid leak, cochlear implant, and functional or anatomic asplenia, administration of Prevnr IN ADDITION to Pneumovax will likely result in increased protection against pneumococcal infection in these high-risk patients, according to ACIP. However, studies show that persons who received Pneumovax 23 as the initial study dose had lower antibody responses after administration of a Prevnr 13 dose 1 year later than those who had received Prevnr 13 as the initial dose.

ACIP issued specific guidance on the use of pneumococcal vaccines:

- Use of Prevnr 13 (*per ACIP recommendations*)
 - **Pneumococcal vaccine-naïve persons.** ACIP recommends that adults aged ≥ 19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, and who have not previously received PCV13 or PPSV23, should receive a dose of PCV13 first, followed by a dose of PPSV23 at least 8 weeks later. Subsequent doses of PPSV23
- Use of Pneumovax 23 -
 - Administer the Pneumovax 23 vaccine to all adults ≥ 65 years of age.
 - Administer the Pneumovax 23 vaccine to adults 19-64 years of age at high risk, including those with chronic



should follow current PPSV23 recommendations for adults at high risk. Specifically, a second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19–64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. Additionally, those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years, or later if at least 5 years have elapsed since their previous PPSV23 dose.

• Previous vaccination with PPSV23. Adults aged ≥ 19 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, who previously have received ≥ 1 doses of PPSV23 should be given a PCV13 dose ≥ 1 year after the last PPSV23 dose was received. For those who require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years after the most recent dose of PPSV23. As stated above, a second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19–64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. Additionally, those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years, or later if at least 5 years have elapsed since their previous PPSV23 dose.

- Use of Pneumovax 23 -
 - Administer the Pneumovax 23 vaccine to all adults ≥ 65 years of age.
 - Administer the Pneumovax 23 vaccine to adults 19-64 years of age at high risk, including those with chronic

(continued on page 3)

Getting the most from our safety surveillance

PREVNAR 13 AND PNEUMOVAX 23

(continued from page 2)

- heart disease; chronic lung disease; diabetes mellitus; cerebrospinal fluid leak; cochlear implant; alcoholism; chronic liver disease; cirrhosis; cigarette smoking; functional or anatomic asplenia; and immunocompromising conditions (i.e., congenital or acquired immunodeficiency; human immunodeficiency virus infection; chronic renal failure; nephritic syndrome; leukemia; lymphoma; Hodgkin disease; generalized malignancy; iatrogenic immunosuppression; solid organ transplant; multiple myeloma).
- Pneumovax 23 should be administered 8 weeks after a pneumococcal vaccine-naïve patient receives Prevnar 13 for the first time.
- When an additional dose of Pneumovax 23 is clinically indicated, ACIP recommends a second Pneumovax 23 dose at least 5 years after the first Pneumovax dose for:
 - Persons \geq 65 years of age who received their first dose when they were younger than 65 years of age;
 - Persons 19-64 years of age with functional or anatomic asplenia and/or immunocompromising conditions.

More information on pneumococcal vaccines is available at the

Centers for Disease Control and Prevention (CDC) website:

- Pneumovax 23: <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-ppv.pdf>
- Prevnar 13: <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-pcv.pdf>

A previous National Center for Patient Safety (NCPS) Topics in Patient Safety (TiPS) article addresses possible look-alike/sound-alike (LA/SA) confusion and provides advice on mitigating this risk. Details are located at: http://www.patientsafety.gov/TIPS/Docs/TIPS_MarApr07.pdf.

REFERENCES:

1. Internal Data.
2. CDC. Licensure of 13-Valent Pneumococcal Conjugate vaccine for Adults Aged 50 years and Older. MMWR 2012; 61: 394-395.
3. CDC. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2012; 61: 816-819.
4. Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee (VRBPAC) adult indication briefing document: Prevnar 13. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2011. Available at <http://www.fda.gov/downloads/advisorycommittees/committees/meetingmaterials/bloodvaccines/andotherbiologics/vaccinesandrelatedbiologicalproductsadvisorycommittee/ucm279680.pdf>. Accessed April 2, 2013.
5. NCPS Topics in Patient Safety. http://www.patientsafety.gov/TIPS/Docs/TIPS_MarApr07.pdf. Accessed April 16, 2013.