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Medication safety in seconds

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

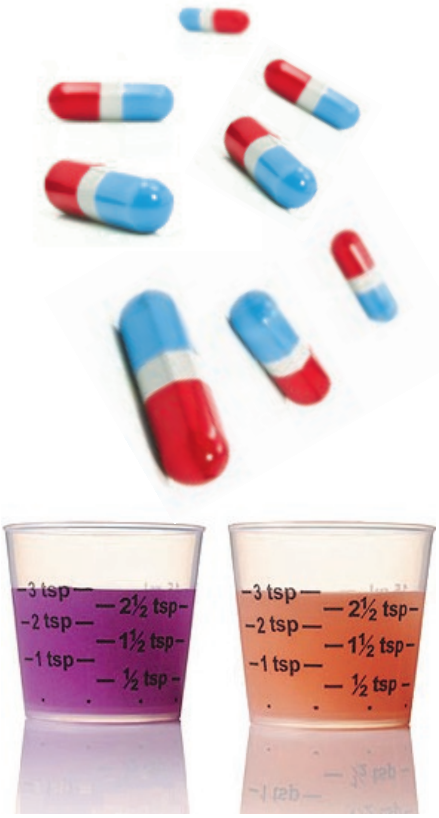
Helping to achieve safe medication use

CUSTOMIZED NCPIE CAMPAIGN FOR SAFE USE OF ACETAMINOPHEN

On May 7, 2012, the National Council on Patient Information and Education (NCPIE), a non-profit alliance of representatives from consumer and patient groups, voluntary health organizations, healthcare professionals, government agencies, and pharmaceutical manufacturers, developed an educational program to raise consumer/patient awareness about the safe and appropriate use of acetaminophen. Three online modules provide customized information regarding safe acetaminophen use for distinct populations across the age spectrum. Module 3 targets the elderly and their caregivers, and can be accessed with the following link: http://mustforseniors.org/acetaminophen_safeuse.jsp . Content includes:

- **Acetaminophen: Know the Facts** – Safe and effective pain relief when used as directed;
- **Be Medicine Smart** -Tips for using medicines safely;
- **Older Adults and Medicine Use** - Important facts;
- **Caregiver Corner** - How to help older adults manage medicines safely;
- **Resources** - Useful external links for learning more about using acetaminophen safely.

This module can be combined with NCPIE's **Medication Use Safety Training *for Seniors*™** program site, located at www.mustforseniors.org , for additional learning materials and tools.



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NEWS YOU CAN USE

FROM THE FOOD AND DRUG ADMINISTRATION (FDA)

NEUROLOGY

Revised recommendations for cardiovascular monitoring and use of multiple sclerosis drug Gilenya (fingolimod)

5/14/2012

FDA's evaluations of one fatal case report, as well as clinical trials and post-marketing data, cannot definitively associate death outcomes from any cause with the multiple sclerosis drug fingolimod (Gilenya®). However, data show that fingolimod (Gilenya®) can induce bradycardia up to 20 hours post-initial dose, contraindicating its use in:

- Patients with certain pre-existing or recent (within 6 months) cardiovascular conditions or stroke; OR
- Patients taking certain cardioarrhythmic medications.

FDA recommends monitoring the following parameters in all patients starting fingolimod (Gilenya®) for at least 6 hours after first dose:

- Heart rate for signs/symptoms of bradycardia;
- Pulse and blood pressure every hour;
- Electrocardiogram (ECG) prior to dosing and at the end of patient's observation period.

FDA recommends extending the monitoring period beyond 6 hours for high risk patients, including those with:

- Severe bradycardia after initial dose (heart rate < 45 beats per minute within the first 6 hours of monitoring or lowest heart rate at 6 hours post-dose due to possibility of further depression);
- Pre-existing conditions affecting bradycardia;
- Concommitant use of medications that slow heart rate or atrioventricular conduction;
- Concommitant use of medications that prolong the QT interval;
- QT interval prolongation before fingolimod (Gilenya®) administration or during the monitoring period.

ONCOLOGY

Safety review update of cancer drug Revlimid (lenalidomide) and risk of developing new types of malignancies

5/7/2012

An FDA review of three clinical trials show an increased risk of developing new primary malignancies when patients receive maintenance therapy with lenalidomide (Revlimid®) compared to placebo after initial chemotherapy alone or after initial chemotherapy in combination with stem cell transplantation. FDA pooled data from 3 prospective randomized trials which demonstrated a nearly 3-fold increase in new malignancies among the groups receiving lenalidomide (Revlimid®) versus groups that did not receive lenalidomide (Revlimid®) [7.9% versus 2.8%, respectively; $p<0.001$]. The new malignancies include acute myelogenous leukemia (AML), myelodysplastic syndromes (MDS), Hodgkin lymphoma, B-cell malignancies, and other new malignancies, with a median time to development for the new malignancy [from the start of lenalidomide (Revlimid®) until diagnosis of the second malignancy] of 2 years. No difference in incidence rates for non-melanoma skin cancer or solid tumors occurred between patients who received lenalidomide (Revlimid®) and those who did not. FDA performed an additional retrospective pooled analysis of data derived from 2 clinical trials supporting the initial approval for lenalidomide (Revlimid®) for relapsed/refractory multiple myeloma, and found no increased incidence of second primary cancers with use of lenalidomide (Revlimid®) in this setting compared to dexamethasone alone. Revisions to product labeling reflect these findings. FDA recommends that providers evaluate the risks and benefits when considering lenalidomide (Revlimid®) as a treatment option, and to monitor patients for secondary malignancies during use of lenalidomide (Revlimid®).

REMINDER

ATTENTION PHARMACISTS: Please remember to take advantage of this shared opportunity and exchange of information for ongoing and/or completed MUEs.

HOW TO ENTER LOCAL MUE INFORMATION

- For VISN-Wide MUEs, visit: http://vaww.national.cmop.va.gov/PBM/medsafe/VISNWide%20MUEs
- For Local Facility MUEs, visit: http://vaww.national.cmop.va.gov/PBM/medsafe/Local%20Facility%20MUEs
- Post information in 3 quick and easy steps:
  1. Click on the link
  2. Upload document
  3. Save and Close
- Please ensure compliance with privacy and security rules.
- For questions and suggestions regarding the MUE Clearinghouse, please contact **Muriel.Burk@va.gov** .

Getting the most from our safety surveillance

6% HETASTARCH IN 0.9% SODIUM CHLORIDE INJECTION (HESPAN®) AND LIDOCAINE HCL AND 5% DEXTROSE INJECTION | POTENTIAL LOOK-ALIKE CONFUSION

One VA facility reported a close call involving the potential mix-up of 6% hetastarch in 0.9% sodium chloride injection (HESPAN®) with lidocaine HCl and 5% dextrose injection due to look-alike packaging with a similar color scheme (see Figure 1). HESPAN® bags are stored in the operating room. Lidocaine bags, while not stored in the operating room, may be administered to multiple patients as infusions for adjunct analgesia. Due to continuing drug shortages, pharmacy purchased HESPAN® product from a new manufacturer (B. Braun Medical Inc.) since others could not provide a supply. The packaging of B. Braun's HESPAN® bears a strong resemblance to that of B. Braun's lidocaine product, which the pharmacy also had in their stock. Inadvertently, one of these similarly-looking lidocaine bags ended up in the same location as the HESPAN®. A Certified Registered Nurse Anesthetist (CRNA) discovered the misplaced product while preparing to give HESPAN® to a patient. The lidocaine bag was neither opened nor administered, averting any patient harm.

HESPAN®, an intravenous (IV) solution, treats hypovolemia via plasma volume expansion. On the other hand, lidocaine in dextrose solution for IV administration has anesthetic and antiarrhythmic effects. Both products occur in IV bags of similar size, shape, and color, and have use in acute care, posing a high likelihood of error if these two bags wound up in the same location during a crisis situation, such as in the operating room. A two-gram lidocaine bag given rapidly to a patient by mistake in the place of an intended HESPAN® bag would result in lethal outcomes.

Unique packaging and color-coding serve as identifiers to help health care providers in differentiating between medication products. However, when circumstances necessitate the use of a different or new manufacturer for a routinely used and recognized medication (as in the event of a drug shortage), product shape, size, and color may also change. If the switch in manufacturers occurs suddenly and without notice, this may create an increased risk for medication error, especially in emergency situations where providers may partially rely on product appearance/color for quick identification of medications.

REFERENCES:

1. Field Information Report.
2. HESPAN® (6% HETASTARCH IN 0.9% SODIUM CHLORIDE INJECTION) [package insert]. Irvine, CA: B. Braun Medical Inc.; April 2003.
3. LIDOCAINE HCL AND 5% DEXTROSE INJECTION [package insert]. Irvine, CA: B. Braun Medical Inc.; January 2011.

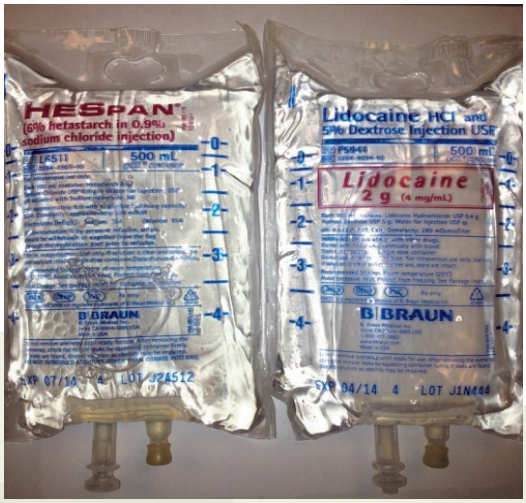

FIGURE 1. 6% Hetastarch in 0.9% sodium chloride injection (HESPAN®) and lidocaine HCl and 5% dextrose injection, both manufactured by B. Braun Medical Inc., use IV bags of similar shape, size, and color, increasing the potential for look-alike confusion.

PROVIDER RECOMMENDATIONS

- Providers should be aware of the potential for look-alike confusion between 6% hetastarch in 0.9% sodium chloride injection (HESPAN®) and lidocaine HCl and 5% dextrose injection due to similar packaging and label color when manufactured by B. Braun Medical Inc.
- Providers should carefully check the name on the IV bag when either 6% hetastarch in 0.9% sodium chloride injection (HESPAN®) or lidocaine HCl and 5% dextrose injection is ordered and/or administered.
- Pharmacy should ensure that a process is in place to return unused stock of 6% hetastarch in 0.9% sodium chloride injection (HESPAN®) and lidocaine HCl and 5% dextrose injection to designated pharmacy or operating room area(s) when not ordered for a particular patient.
- Pharmacy should review their stock for 6% hetastarch in 0.9% sodium chloride injection (HESPAN®) and lidocaine HCl and 5% dextrose injection, and ensure that a method is in place to distinguish between the two agents in order to avoid future look-alike confusion (i.e., warning stickers/labels).
- Pharmacy should ensure that a system is in place to notify providers regarding the use of new manufacturers and/or new product appearance/packaging to reduce the potential for medication error, especially for critical drug products used in acute or emergency care.