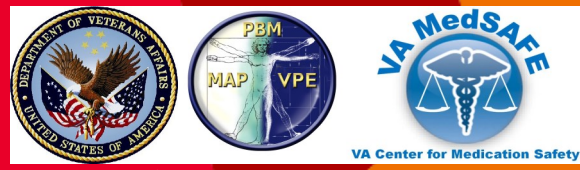


- ▶ GLACIAL ACETIC ACID: PRODUCT CONFUSION AND SEVERE BURNS 1
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○ ISSUE 3 | ○ VOLUME 3 | ○ MARCH 2013

Medication *safety in seconds*

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

Helping to achieve safe medication use

GLACIAL ACETIC ACID: PRODUCT CONFUSION AND SEVERE BURNS

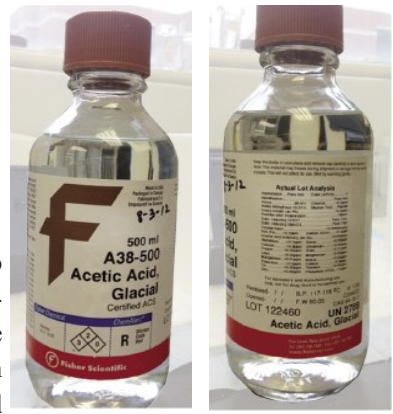
Health care staff have confused glacial acetic acid (the most concentrated form of acetic acid available), for diluted acetic acid (commonly known as vinegar), with inadvertent application of glacial acetic acid resulting in severe burns, scarring, and permanent damage to skin as well as mucous membranes. Acetic acid, in diluted formulations, has several uses which include identification of dysplasia of mucous membranes (3-5% solution); treatment of infections of the outer ear and ear canal (2% solution); and irrigation of wound areas (0.25% sterile solution). On the other hand, glacial acetic acid ($\geq 99.5\%$) is a corrosive chemical and solvent used in laboratory settings, and has no applications medically.

Glacial acetic acid does not fall under the regulation of the Food and Drug Administration (FDA), and product labeling is not

standardized with respect to warnings about the chemical's corrosive nature. The Institute of Safe Medication Practices (ISMP) has reported product labeling inconsistencies as a contributing factor to product confusion in an effort to raise awareness and help the chemical industry to improve warning systems. In order to avoid future product confusion, health care staff should:

- Eliminate the use and/or purchase of glacial acetic acid; and
- Only use diluted acetic acid in patient.

REFERENCES:
NAN ALERT. WARNING! Severe burns and permanent scarring after glacial acetic acid ($\geq 99.5\%$) mistakenly applied topically. National Coordinating Council on Medication Error Reporting and Prevention (NCCMERP): January 23, 2013.



NEWS YOU CAN USE

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

CARDIOLOGY

Dual Renin-Angiotensin Aldosterone System Blockade and Impaired Renal Function and Hyperkalemia – 02-12-2013 - [National PBM Bulletin](#)

NEWS YOU CAN USE

FROM THE FOOD AND DRUG ADMINISTRATION (FDA)

DIABETES

[FDA investigating reports of possible increased risk of pancreatitis and pre-cancerous findings of the pancreas from incretin mimetic drugs for type 2 diabetes](#)

3/14/2013

Unpublished new findings from a group of academic researchers indicate a possible increased risk of pancreatitis and pancreatic duct metaplasia (pre-cancerous cellular changes) in patients with type 2 diabetes treated with incretin mimetics (exenatide [Byetta, Bydureon], liraglutide [Victoza], sitagliptin [Januvia, Janumet, Janumet XR, Juvisync], saxagliptin [Onglyza, Kombiglyze XR], alogliptin [Nesina, Kazano, Oseni], and linagliptin [Tradjenta, Jentadueto]). Data ensued from examination of pancreatic tissue specimens taken from patients following death from unspecified causes. Currently, drug labels and patient Medication Guides for incretin mimetics contain warnings about the risk of acute pancreatitis (fatal and serious nonfatal cases) associated with these agents. FDA continues to investigate pancreatic toxicity associated with incretin mimetics and will issue any recommendations or conclusions upon completion. Health care professionals should continue to follow the prescribing recommendations in the drug labels for this drug class; and patients should continue to take their medicine as directed.

INFECTIOUS DISEASE

[Azithromycin \(Zithromax or Zmax\) and the risk of potentially fatal heart rhythms](#)

3/12/2013

Azithromycin, a broad-spectrum macrolide antibiotic, increases the risk of QT-interval prolongation, torsades de pointes, polymorphic ventricular tachycardia, and sudden cardiac death as demonstrated in a study published last year by the New England Journal of Medicine (previously discussed in [Issue 8; Volume 2; September 2012](#) of VA's Medication Safety in Seconds newsletter) as well as a clinical QT study conducted by the manufacturer. Updated product labeling now includes this new information. FDA recommends that health care professionals should weigh the risks of torsades de pointes and fatal arrhythmia versus benefits when considering treatment options with azithromycin or alternative antibiotics, bearing in mind that other macrolide and fluoroquinolone agents may also potentiate QT interval prolongation as well as impart other serious side effects. Patients at higher risk of an adverse cardiac event include the elderly and those with pre-existing cardiac disease, including:

- Known prolongation of the QT interval, a history of torsades de pointes, congenital long QT syndrome, bradyarrhythmias, or uncompensated heart failure;
- Concomitant drug therapy known to prolong the QT interval; and
- Ongoing proarrhythmic conditions such as uncorrected hypokalemia or hypomagnesemia, clinically significant bradycardia, and in patients receiving Class IA (quinidine, procainamide) or Class III (dofetilide, amiodarone, sotalol) antiarrhythmic agents.

*Note: One VA Medical Center added the following verbiage to the ordering template for AZITHROMYCIN: “**May Prolong QTc—use cautiously in patients at risk***”. This may serve as one option for how to inform providers at the site level within the VA of this safety risk.*

Dosage / Rate	Complex	Route	Schedule
250MG	0.5827	MOUTH	
250MG	1.0133	ORAL	0900-1700
500MG	1.1654	NG TUBE	1-5-9
500MG	2.0266		1AM
600MG	2.1983		1P9P
			1PM
			5-1-5
			5A1P
			5A5P
			5AM
			5XDAILY
			6XDAILY
			730AM
			9-1-5
			9-1-9
			9A5P
			AM

(continued on page 3)

Getting the most from our safety surveillance

USE OF MULTI-DOSE PEN INJECTORS



**BE AWARE
DON'T SHARE**

The VA National Center for Patient Safety has addressed the issue of multi-dose pen injectors on 2 occasions: previously in 2008 due to an incident of use of the same multi-dose heparin syringe for intravenous line flushes on multiple patients; and more recently in January 2013 with the discovery in a VA facility of several insulin pen injectors not labeled for individual patients but instead used to administer doses of insulin to different patients by changing the needle between each patient. **Multi-dose pen injectors are intended for use by one patient only.** Sharing the pen injector and cartridges may put patients at risk for exposure to blood-borne pathogens like Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), or Human Immunodeficiency Virus (HIV). This resulted in an internal policy which prohibits the use of multi-dose pen injectors (Table 1) on all patient care units, with the following exceptions:

- Patients being educated prior to discharge to use a patient-specific multi-dose pen injector.

- Eligible patients participating in the VA medical center's Self-Medication Program (SMP) as established by VHA Handbook 1108.03.
- Patients requiring treatment with a medication delivered in a multi-dose pen injector, and no alternative formulation is available from the manufacturer for treating the patient while on a patient care unit (Table 2).
- Patients participating in a research protocol requiring a multi-dose pen injector while on a patient care unit.
- Pen injectors dispensed directly to the patient as an outpatient prescription.

In these excepted instances, health care staff should ensure that:
(continued on page 4)

NEWS YOU CAN USE

FROM THE FOOD AND DRUG ADMINISTRATION (FDA)

(continued from page 2)

ENDOCRINE

[FDA suspends pediatric clinical trials of Sensipar \(cinacalcet hydrochloride\) after report of death](#)

2/26/2013

FDA has put a stop to all pediatric clinical trials of cinacalcet hydrochloride (Sensipar®) following the death of a 14-year old patient during one of the trials. FDA continues to gather and evaluate information concerning the event and will communicate any final conclusions and/or recommendations upon completion of their review. Cinacalcet hydrochloride (Sensipar®) is a calcium-sensing receptor agonist indicated for:

- Secondary hyperparathyroidism in patients with chronic kidney disease;
- Hypercalcemia in patients with cancer of the parathyroid; and
- Severe hypercalcemia in patients with primary hyperparathyroidism unable to undergo parathyroidectomy.

Cinacalcet hydrochloride (Sensipar®) currently does not have FDA approval for use in children.

PAIN MANAGEMENT

[Safety review update of codeine use in children; new Boxed Warning and Contraindication on use after tonsillectomy and/or adenoidectomy](#)

2/20/2013 *** UPDATE FROM 08/15/2012***

In August 2012, FDA reviewed codeine use and associated rare, but life-threatening, adverse events or death in certain children after tonsillectomy and/or adenoidectomy. FDA's Adverse Event Reporting System (AERS) contained 13 cases of pediatric death or overdose associated with codeine use in patients ranging in age from 21 months old to 9 years old post-adenotonsillectomy or respiratory tract infection. Seven of these cases appeared in the medical literature where they were categorized as ultra-rapid metabolizers. FDA identified 2 additional cases of pediatric death associated with codeine use in autopsy-confirmed ultra-rapid metabolizers while conducting a review of a physician survey on morbidity and mortality following tonsillectomy and/or adenoidectomy conducted by the American Academy of Otolaryngology – Head and Neck Surgery. In light of these reports, FDA will update product labeling with the following:

- A new *Boxed Warning* regarding the risks of codeine use in children following tonsillectomy and/or adenoidectomy;
- A *Contraindication* applying to all children undergoing tonsillectomy and/or adenoidectomy due to difficulty in determining which children may be ultra-rapid metabolizers of codeine; and
- Revised *Warnings/Precautions*, *Pediatric Use*, and *Patient Counseling* information sections.

Getting the most from our safety surveillance

USE OF MULTI-DOSE PEN INJECTORS

(continued from page 3)

- Multi-dose pen injectors shall be stored in the pharmacy and dispensed with an individual patient label consistent with the VA facility's labeling requirements. Multi-dose pen injectors shall not be ward stocked.
- Multi-dose pen injectors are to be used by a single patient only and should never be shared with other patients, even when the needle is changed.
- Disposable safety needles with shield guards must be used to ensure OSHA compliance on patient care units. The needles should be promptly and properly discarded after each injection and a new safety needle attached prior to each additional injection.
- Education on facility policy and safe use of pen injectors must be provided to applicable current and new employees, and be a part of their annual competency assessment.

REFERENCES:

1. Patient Safety Alert 08-02. Same syringe used for IV (intravenous) line heparin flushes for multiple patients. VA National Center for Patient Safety (NCPS): August 8, 2008.
2. Patient Safety Alert 13-04. Multi-Dose Pen Injectors. VA National Center for Patient Safety (NCPS): January 17, 2013.
3. Department of Veterans Affairs. VHA Handbook 1108.03. Self-Medication Programs (SMP). February 3, 2010. http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2166
4. Internal Policy.

TABLE 1. Multi-Dose Pen Injectors Available in Alternative Formulations

Generic Name	Brand Names
Insulin Pen Injectors	
Insulin Glargine	Lantus® SoloStar®
Insulin Detemir	Levemir® FlexPen®
Insulin Glulisine	Apidra® SoloStar®
Insulin Aspart	Novolog® FlexPen®
Insulin Aspart Protamine/ Insulin Aspart	Novolog® Mix 70/30 FlexPen®
Insulin Lispro	Humalog® KwikPen™
Insulin Lispro Protamine/ Insulin Lispro	Humalog® Mix 75/25 KwikPen™, Humalog® Mix 50/50 KwikPen™
Insulin NPH	Humuline® N Pen
Insulin NPH/ Insulin Regular	Humuline® 70/30 Pen
Miscellaneous Pen Injectors	
Follitropin Alfa	Gonal-F® RFF Pen
Follitropin Beta	Follistim® AQ
Interferon Alfa-2b	Intron® A
Somatropin	Norditropin FlexPro®, Nutropin AQ Pen®, Omnitrope®, Humatropen®, Nutropin® AQ NuSpin™, Norditropin® NordiFlex®

TABLE 2. Multi-Dose Pen Injectors Unavailable in Alternative Formulations

Generic Name	Brand Names
GLP-1 Receptor Agonist Pen Injectors	
Exenatide	Byetta®
Liraglutide	Victoza®
Pramlintide	SymlinPen®
Miscellaneous Pen Injectors	
Apomorphine	Apokyn®
Teriparatide	Forteo