Key Causes of Medication Errors and Strategies for Improvement

WHO Global Challenge on Medication Safety
Bonn Germany
March 29, 2017

Allen J. Vaida, BSc., PharmD
Executive Vice President
Institute for Safe Medication Practices
www.ismp.org

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Institute for Safe Medication Practices

- A Not-for Profit Charity (501c3)
  – multi-disciplinary (pharmacists, nurses, physicians)
- Interacts with but independent of regulatory, standard setting, or accrediting organization
- Relies on healthcare professionals and consumers to supply information on medication errors (ISMP National Medication Errors Reporting Program – MERP)
- Mission: To advance patient safety worldwide by empowering the healthcare community, including consumers, to prevent medication errors

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

WHO Global Challenge on Medication Safety

- "Many countries lack data about medication safety…
- "High-income countries are more likely to posses robust medication safety systems…However, errors still occur…indicating that focused efforts…may diminish the threat"
- "Systems approach is needed to build a safety net to catch errors before they reach the patient…rather than solely relying on the actions of individuals"

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

What We are Hearing from Others

- Need for accurate medication histories/lists to improve medication reconciliation at all transitions of care
- Need to focus efforts on high risk patients and high-alert medications
- Issues with polypharmacy
- Need for better and authorized patient information/education
- Listen to and involve the patient

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Other Key Causes of Medication Errors

- Similar medication –
  - Nomenclature, Labeling/Packaging
- Ambiguous display of concentration or strength
- Lack of warnings on ampules'/vials
- Unavailability of pre-mixed medications for intravenous use leading to preparation of medications by nurses
- Lack of universal bar codes
- Lack of Harmonization within countries and internationally
- Lack of medication safety ‘advocates’

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

US

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

US

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Spain

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Latin America - Colombia

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

US

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Vaccine Error in Brasil

Alerta de Segurança!

ismp Brasil

Atenção, Profissionais de Saúde!
Previnam a troca de frascos de vacina contra a gripe!

O frasco ampola da vacina contra a gripe (influenza) é semelhante aos frascos de outros medicamentos armazenados sob refrigeração (na geladeira) como, por exemplo, a insulina. Essa semelhança pode contribuir para **TROCA** no momento do preparo e administração da vacina.

O **ISMP Brasil** apresenta algumas recomendações para prevenir erros de administração desta vacina. O principal objetivo é implantar **BARREIRAS** que reduzam, dificultem ou eliminem a possibilidade da ocorrência de troca de frascos.

ARMAZENAMENTO SEGURO:

- Armazenar a vacina **separada** dos demais medicamentos sob refrigeração.
- Se a vacina for armazenada na mesma geladeira que outros medicamentos, colocá-las em **caixas e prateleiras diferentes.**
- A **insulina** também deve sempre ser armazenada em local diferente, pois é um Medicamento Potencialmente Perigoso (vide Boletim ISMP Brasil - "Erros de medicação, riscos e práticas seguras na terapia com insulinas").

UTILIZAR ETIQUETAS DE ALERTA:

- Os locais de armazenamento das vacinas e das insulinas, dentro e fora da geladeira, devem ser identificados com uma **etiqueta de alerta** que as diferencie. Também é importante diferenciar as vacinas umas das outras.

CHECAGEM ANTES DO PREPARO E ADMINISTRAÇÃO:

- **Ler o rótulo** diversas vezes antes de iniciar o preparo da vacina.
- Solicitar ao **paciente/acompanhante** que confira o frasco de vacina junto ao profissional responsável pelo seu preparo e administração.

INFORMAR OS PROFISSIONAIS DE SAÚDE

- Divulgar os riscos de troca entre os frascos de vacinas e insulina.

ISMP Brasil 10 anos

Para se informar mais sobre segurança de embalagens e rotulagem leia o documento ANSM "Position Statement on Safer Design of Vaccines Packaging and Labelling" elaborado com a participação do ISMP Brasil (Disponível em: http://www.ansm.sante.fr/Nos-activites/Nos-papiers/Safer-packaging-and-labelling)

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

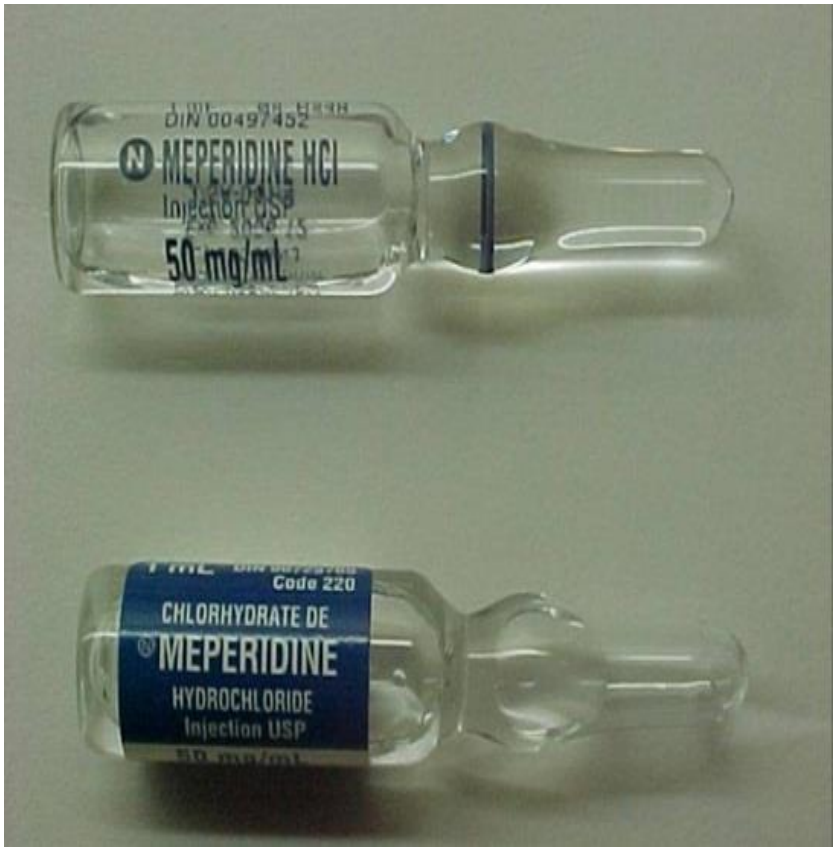
Spain

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

US

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Canada



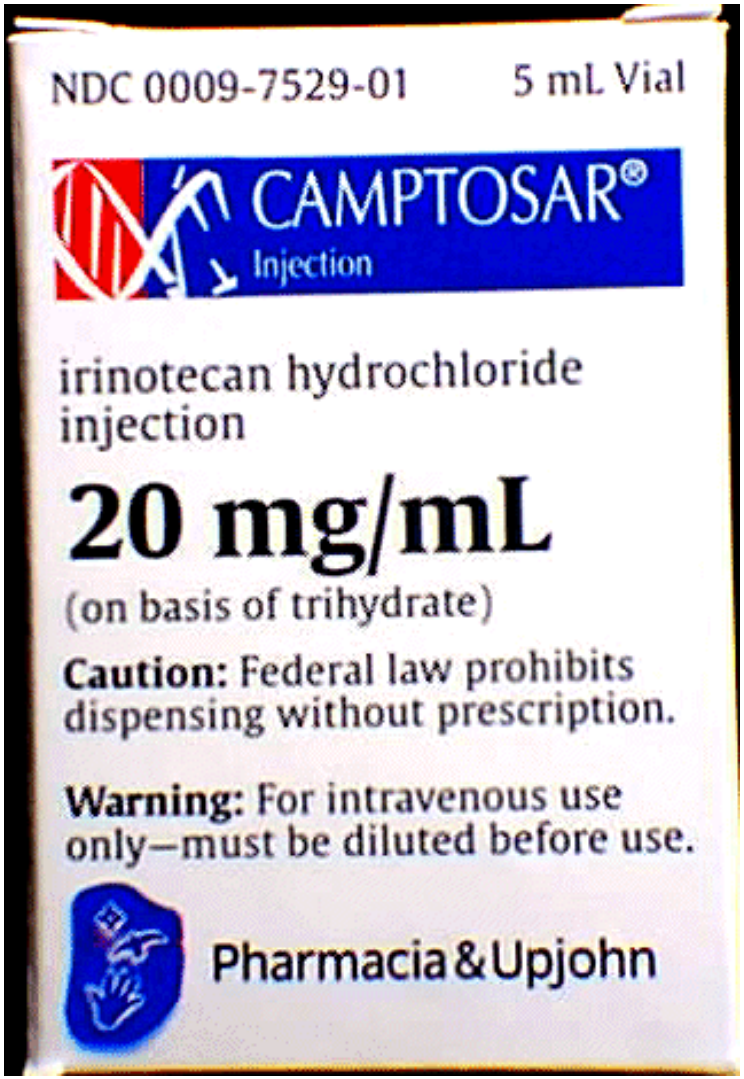
ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

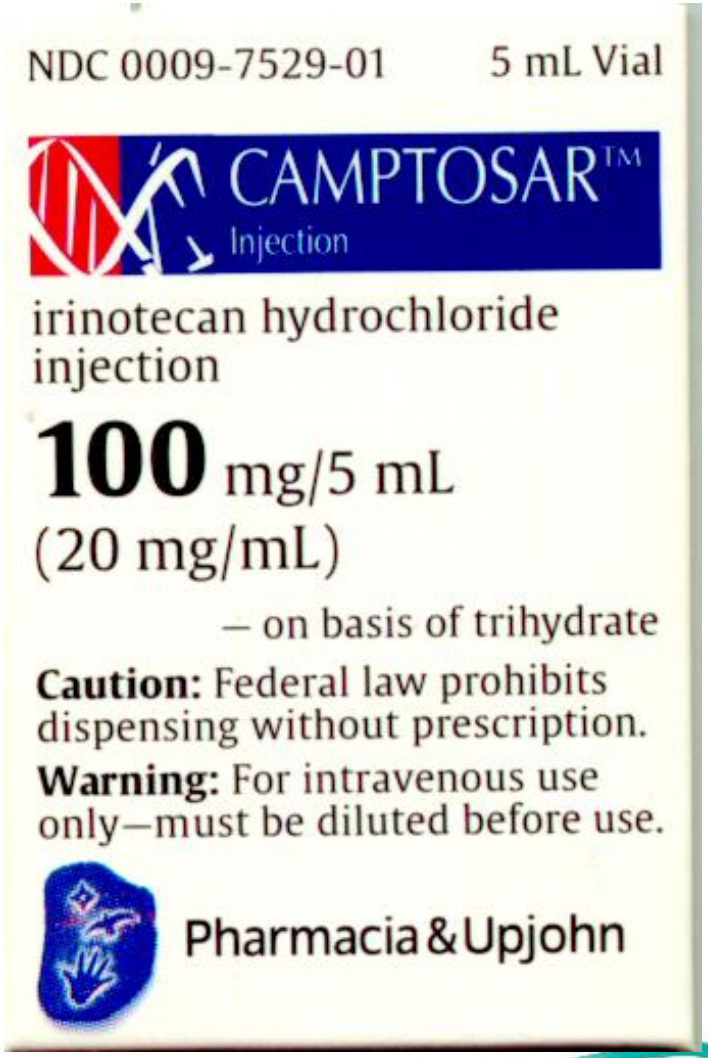
France

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

US

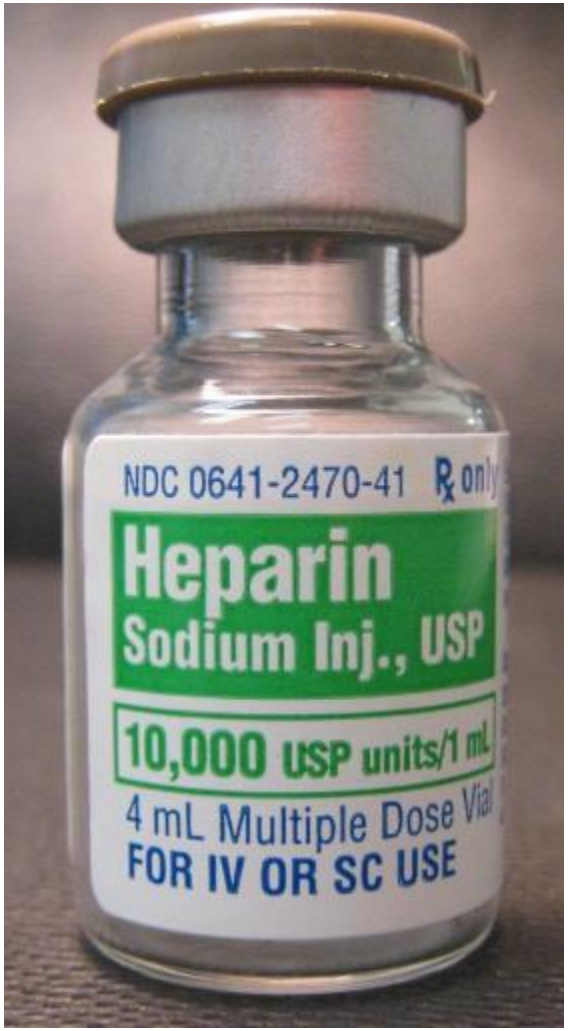
ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES





ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

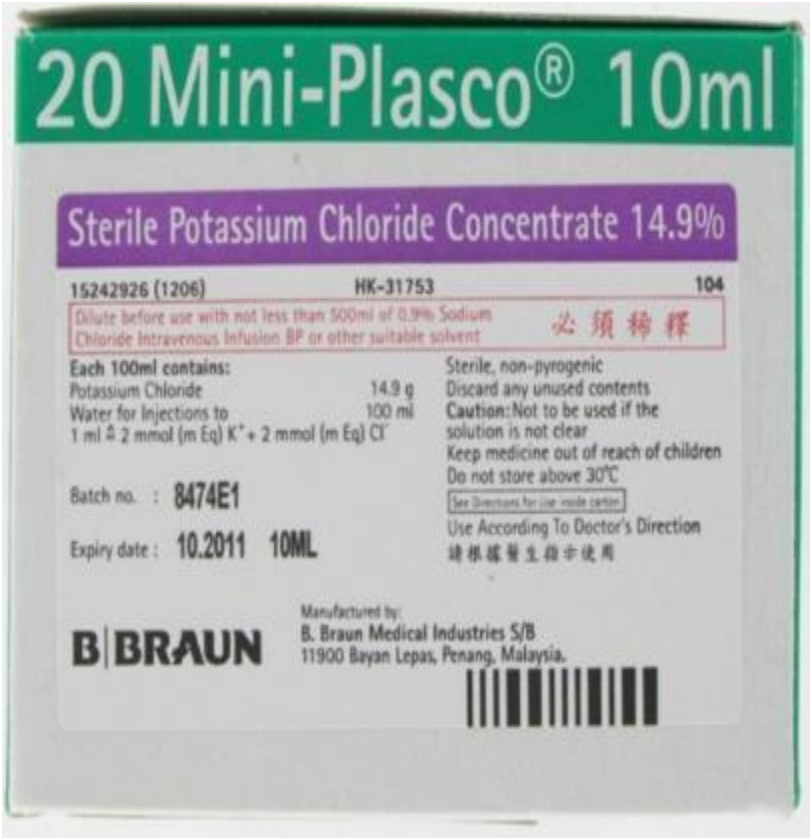


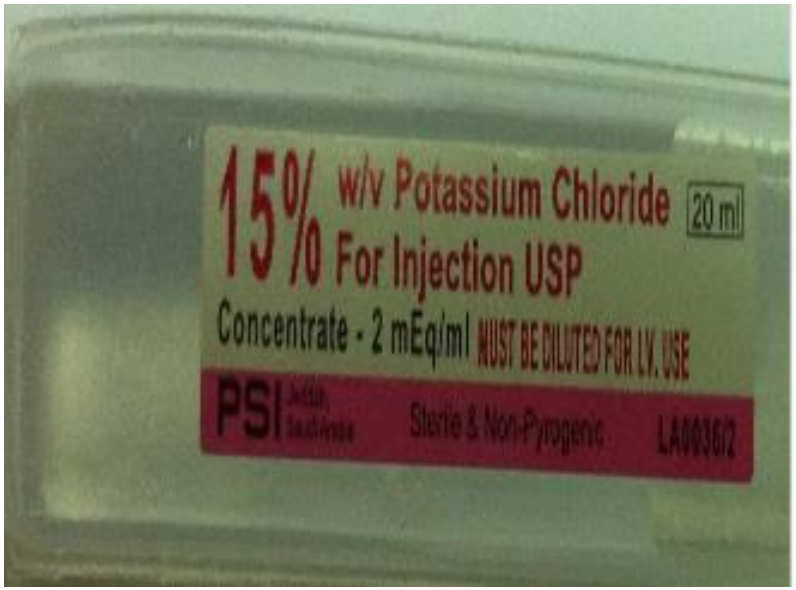
ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Outsourcing in the US

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

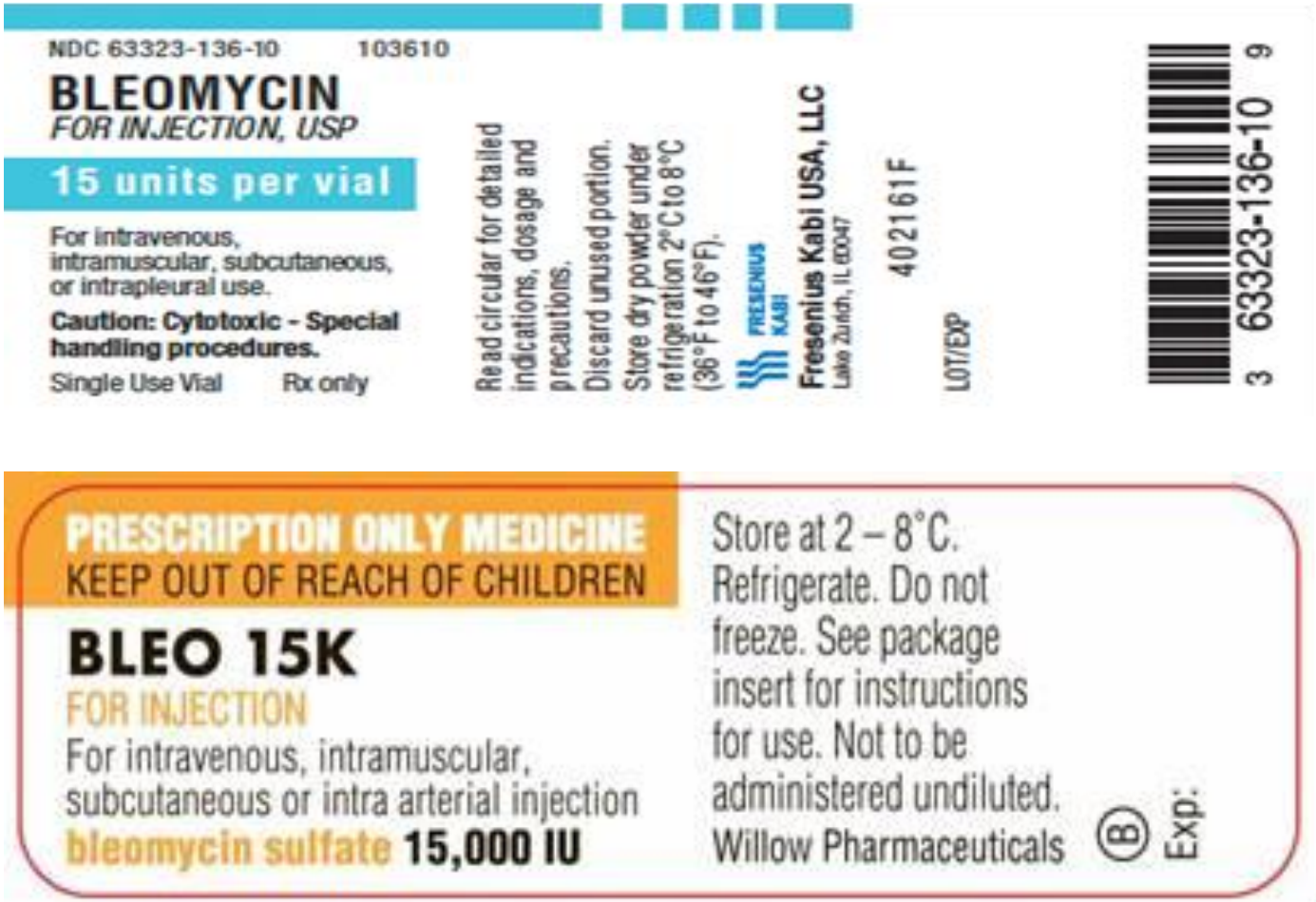
Malaysia and Saudi Arabia





ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Drug Shortages and Importation



ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Unsafe Products

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Watch Live President Obama chairs U.N. Security Council meeting on world terrorism

CBSNEWS Video US World Politics Entertainment Health MoneyWatch SciTech Crime Sports Photos

AP September 17, 2014, 5:31 PM

15 Syrian children die after measles vaccinations

Two Syrian children receive treatment after they were given a second round of measles vaccinations in Idlib province in this photo released Wednesday Sept. 17, 2014, by Edlib News Network (ENN), an activist group opposed to Bashar Assad's government. EDLIB NEWS NETWORK

Comment / 23 Shares / Tweets / Stumble / Email More+

BEIRUT – At least 15 children died after receiving vaccinations in rebel-held parts of northwestern Syria, while the death toll from two days of government airstrikes on a central city climbed to nearly 50, a heavy toll even by the vicious standards of the country's civil war, activists said.

The children, some just babies, all exhibited signs of "severe allergic shock" about an hour after they were given a second round of measles vaccinations in Idlib province on Tuesday, with many suffocating to death as their bodies swelled, said physician Abdullah Ajaj, who administered the vaccinations in a medical center in the town of Jarjanaz.

Most Popular

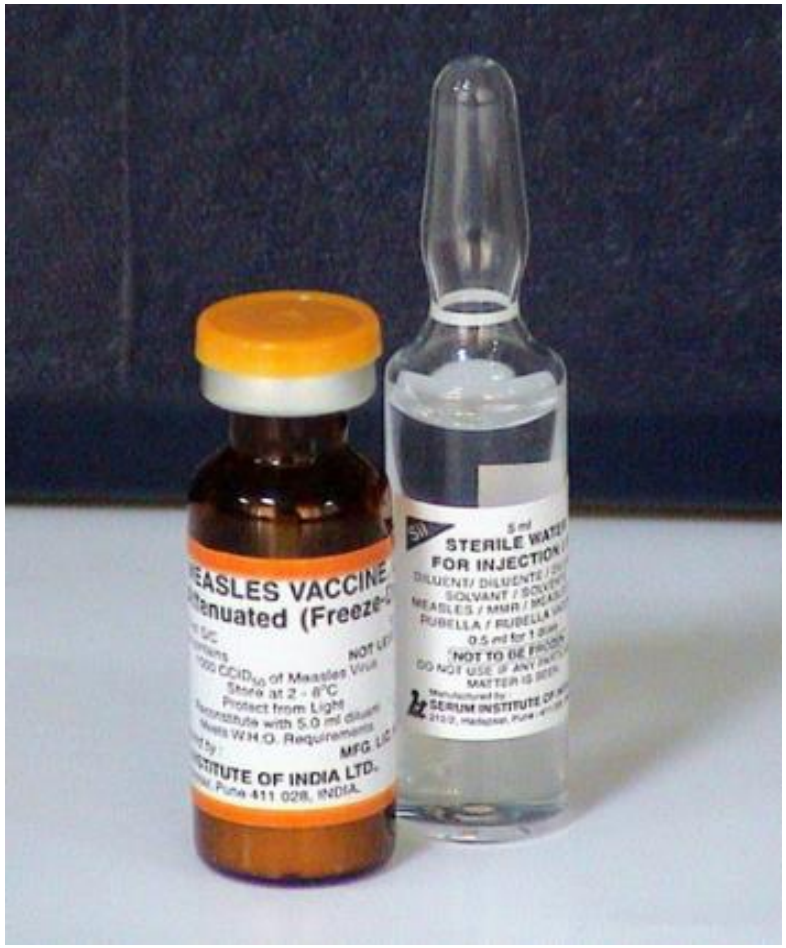
01 Wife of CBS Senior VP hit by bicyclist, dies
177866 views

02 New photos show age, decline of pop music icon in prison
132346 views

03 Zuckerberg making few "friends" in new neighborhood
117160 views

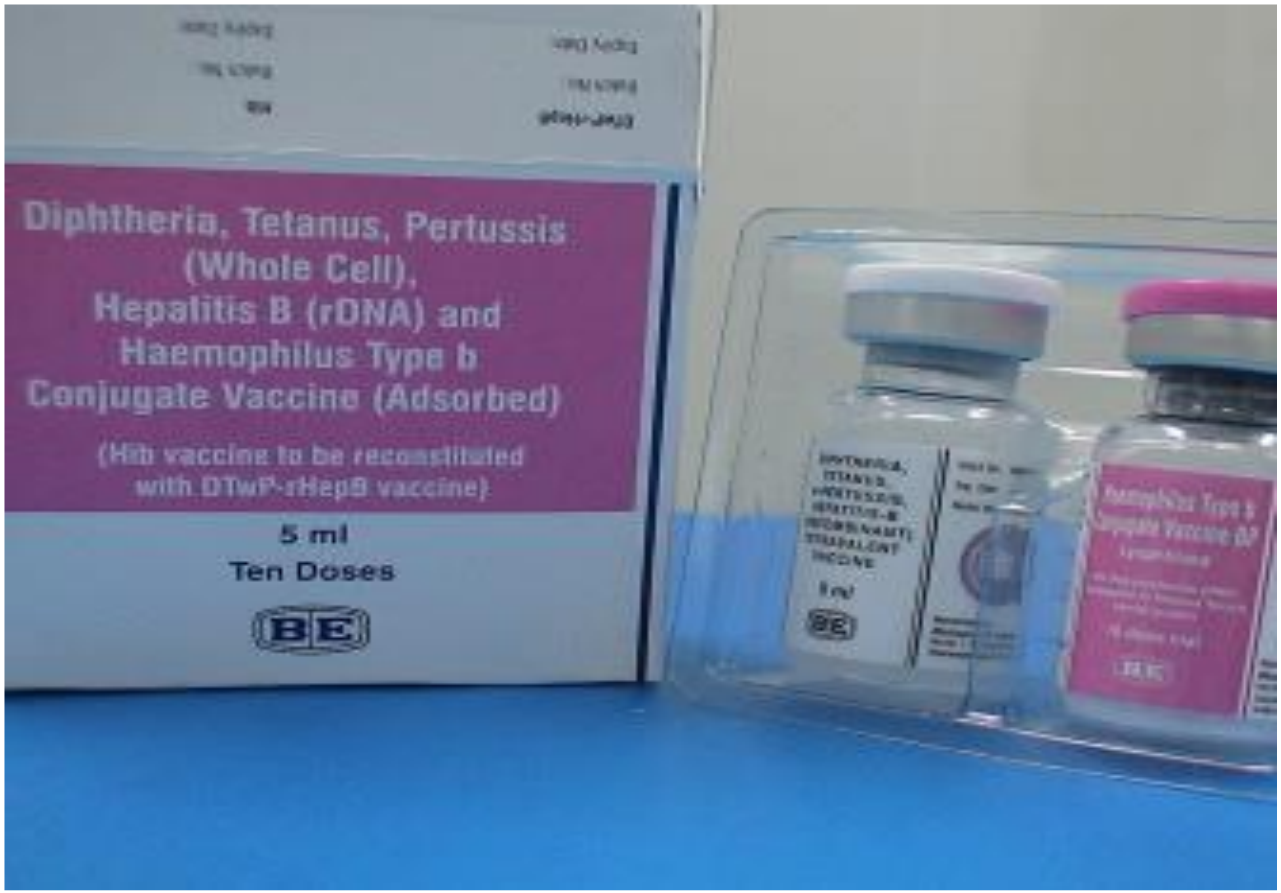
04 Khorasan: Behind the group "following bin Laden's vision"
91113 views

05 The U.S. launches first airstrikes against ISIS in Syria.
70716 views



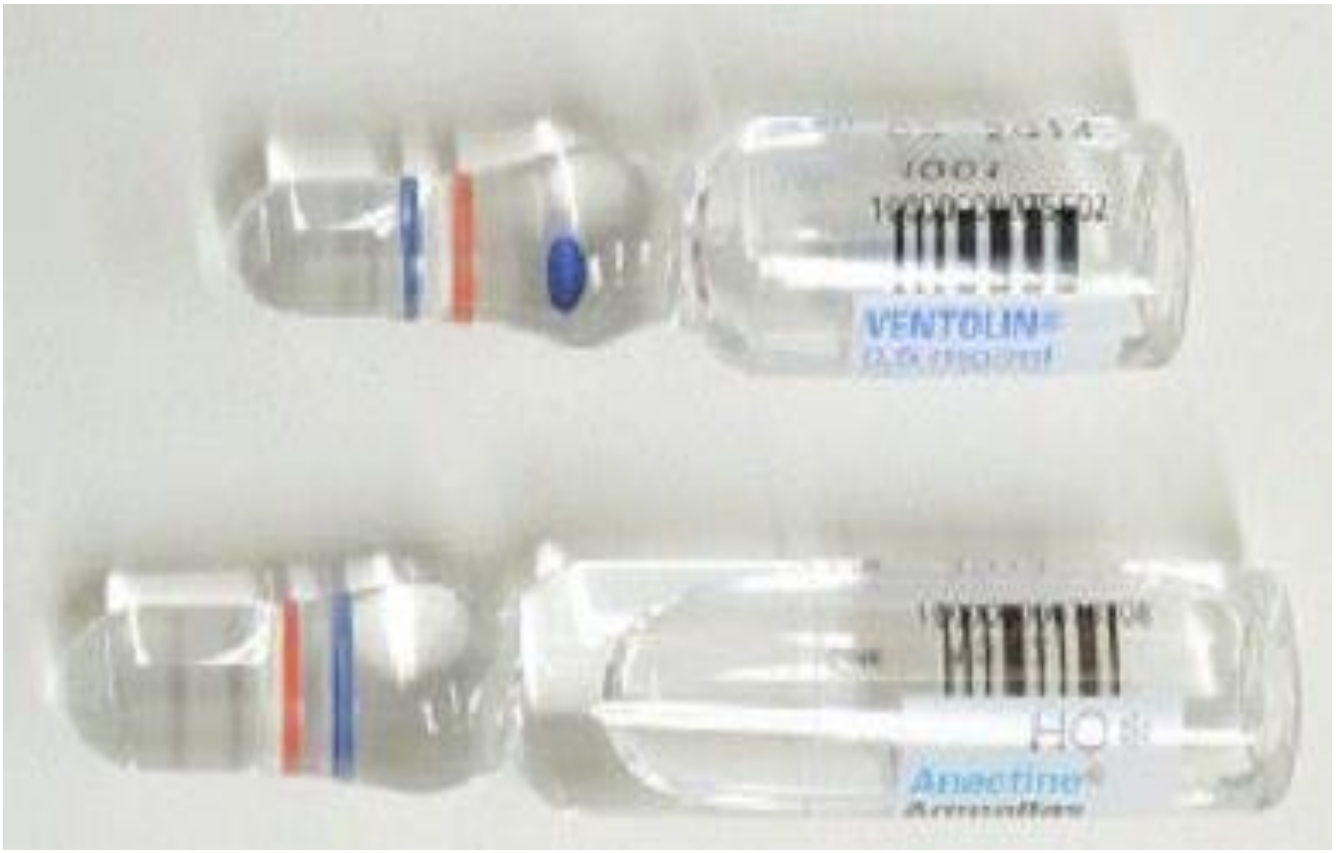
ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Vaccine Diluent Packaging



ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Neuromuscular Blocking Agents Spain



ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Neuromuscular Blocking Agents New Zealand

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

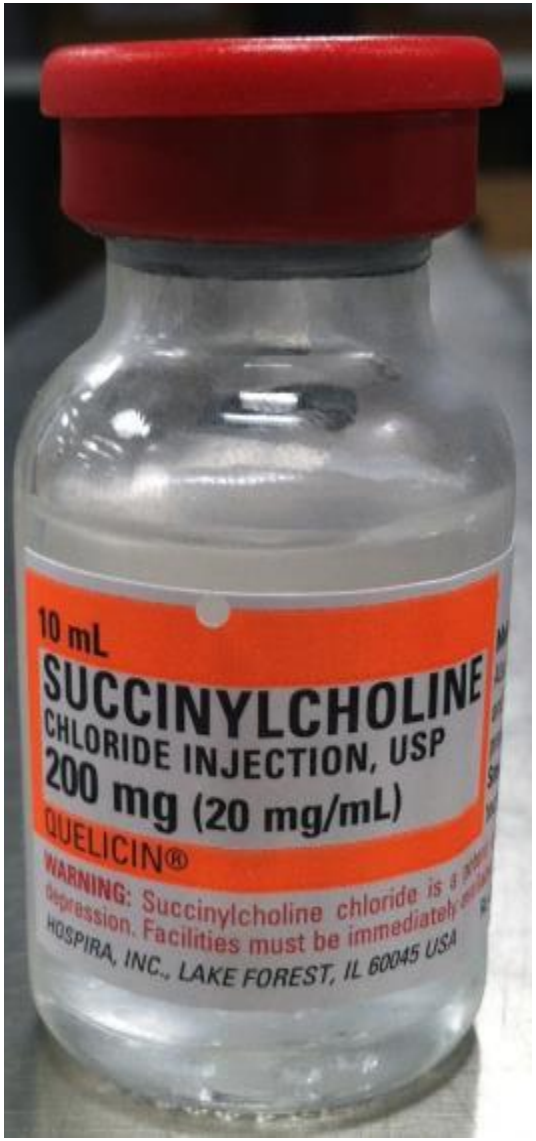
United States Pharmacopeia (USP) Chapter 31

Neuromuscular Blocking and Paralyzing Agents

- All injectable preparations of neuromuscular blocking agents and paralyzing agents must be packaged in vials with a cautionary statement printed on the ferrules or cap overseals. Both the container cap ferrule and the cap overseal must bear in black or white print (whichever provides the greatest color contrast with the ferrule or cap color) the words: “Warning: Paralyzing Agent” or “Paralyzing Agent” (depending on the size of the closure system). Alternatively, the overseal may be transparent and without words, allowing for visualization of the warning labeling on the closure ferrule.

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

With Warnings



ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Regulatory Achievements on an International Scale

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Regulatory Improvements

- FDA/US – April 2016
  - Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products
- Health Canada – June 2016
  - Good Label and Package Practices Guide for Prescription Drugs and Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Regulatory Improvements

- Council of Europe – June 2016
  - Resolution on good reconstitution practices in health care establishments for medicinal products for parenteral use and
  - Resolution on the quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients

Regulatory Improvements

- European Medicines Agency (EMA) – June 2016
  - Described the key concepts of the European Unit good practice guidance for defining, classifying, coding, reporting, evaluating and preventing medication errors.

  Goedecke T, Ord K, Newbould V, Brosch S, Arlett P. Medication Errors: New EU Good Practice Guide on Risk Minimisation and Error Prevention. Drug Saf. 2016; 39 (6): 491-500.

the helen hamlyn research centre

NHS National Patient Safety Agency

Design for patient safety

A guide to the graphic design of medication packaging

Second edition

Health Canada | Santé Canada

Your health and safety... our priority. | *Votre santé et votre sécurité... notre priorité.*

Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products

June 30, 2016

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Guidance for Industry

Best Practices in Developing Proprietary Names for Drugs

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov/ Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis, Kellie Taylor at 301-796-0157, or (CBER) Office of Communications, Outreach and Development at 800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2014
Drug Safety

Guidance for Industry

Safety Considerations for Product Design to Minimize Medication Errors

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov/ Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER), Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis, Carol Holquist at 301-796-0171.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

December 2012
Drug Safety

Still Work to be Done

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

IMSN Global Regulatory Meeting Toronto October, 2016

- Meet with regulators to share their views and concerns on labelling, packaging and nomenclature issues prone to medication errors and to further establish a consensus on a shared action plan for improving medication safety at the global level in coordination with the WHO Global Challenge on Medication Safety.

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Additional Efforts

- Regulatory, Government, and Industry interventions
  - Universal bar codes
  - Harmonization of labelling/packaging and the availability of ready to use products
- Improving regulatory agencies and industry efforts prior to the marketing authorization
- Raising awareness and learning from medication errors reporting programs and pharmacovigilance efforts in all countries
- Medication Safety Champions/Medication Safety Officers in hospitals and/or at a country level to help disseminate learnings from other countries

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES