Institute for Safe Medication Practices
An ECRI Affiliate

ISMP Medication Error Reporting

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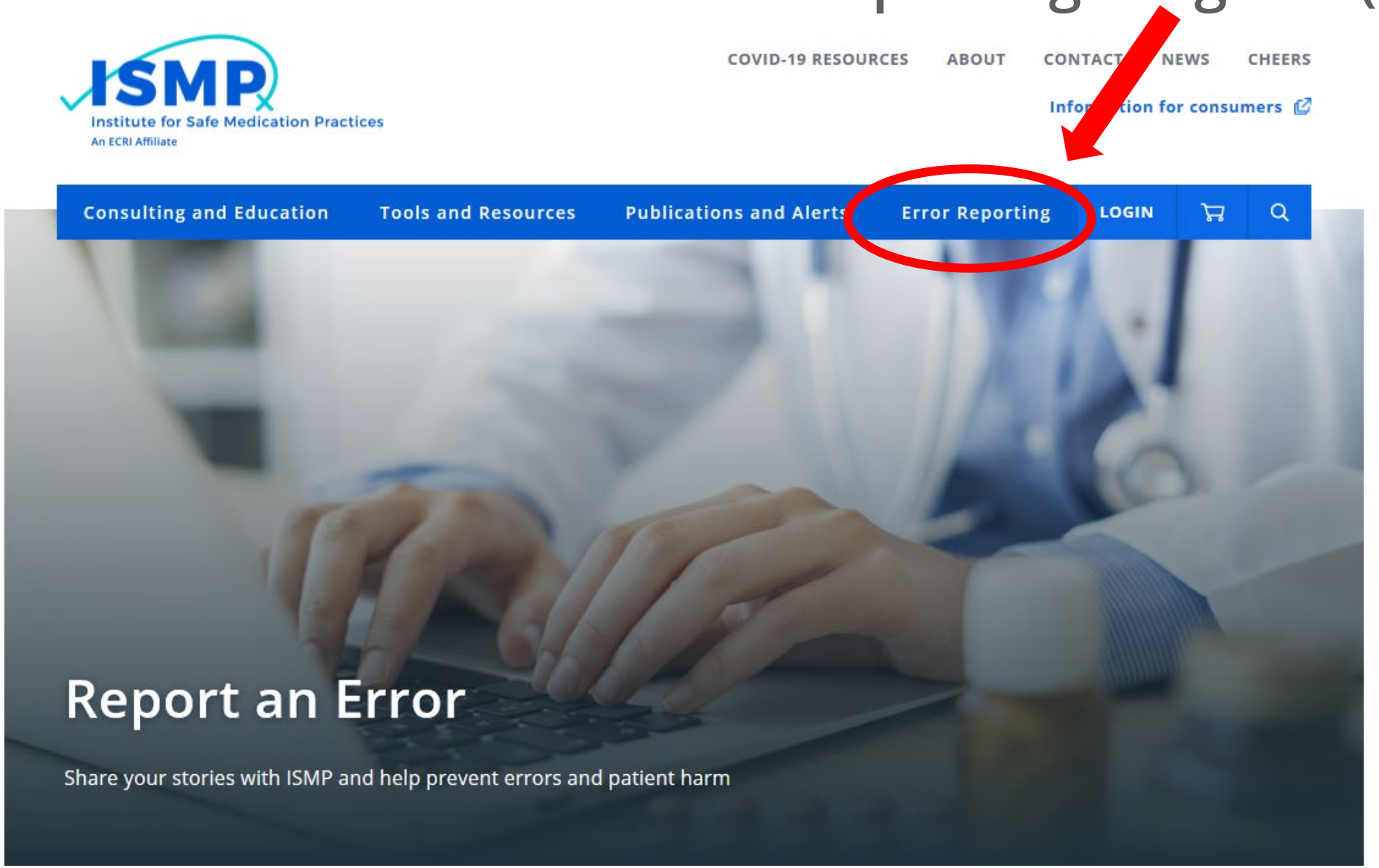
President

Institute for Safe Medication Practices (ISMP)

ISMP National Medication Errors Reporting Program (MERP)



What Do We Do With the Reports?

REPORT

- Healthcare practitioners/ consumers submit medication error reports through ISMP's error reporting programs
- Staff follow up with reporter

INVESTIGATE

- Investigate to determine cause & severity of error
- Work with our network of advisors to assess implication & risks

INFORM

- Promptly inform healthcare community through:
  - Newsletters
  - Educational events
  - Alerts
  - Articles in trade journals

PREVENT

- Interacts with FDA & USP to influence regulatory change
- Works with manufacturers, standards organizations, professional/trade organizations & healthcare community to effect change
- Provides proactive risk assessments and educational services

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FDA MEDWATCH PARTNER

https://ismp.org/error-reporting/what-we-do-your-report

Who Does ISMP Work With?

- U.S. Food & Drug Administration (FDA)
- United States Pharmacopeia (USP)
- The Joint Commission
- National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)
- National Patient Safety Collaborative
- Medical product industry

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U.S. Food & Drug Administration (FDA)

- Tall man (mixed case) lettering for look-alike drug names (**EPINEPH**rine - e**PHED**rine)
- FDA Barcode Rule
- Vincristine in minibag
- FDA Guidance: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors

Report: Wrong drug killed boy

By KAREN GARLOCH
Staff Writer

The N.C. medical examiner's office has concluded that an overdose of the wrong medicine killed a 5-year-old Shelby boy at Duke University Medical Center in February.

Brandon Aly Quintero died Feb. 22, two weeks after he received the wrong medication for treatment of a benign tumor on his left forearm.

Brandon

An autopsy, made public Friday, shows Brandon received vincristine, an anti-cancer drug, instead

Wrong spinal drug fatal to 3-year-old boy with Down syndrome

HARRISBURG (AP) — A 3-year-old Middletown boy with Down syndrome died at ____ Medical Center after a second-year resident accidentally injected a toxic drug into his spinal canal, according to the Patriot-News.

Dr. Michelle Reilly was never disciplined for the mistake, which the Dauphin County Coroner's office concluded was responsible for the death of Michael Lee Sozookie.

The accident happened on March 2 when Reilly was instructed to administer one drug into Michael's spinal canal and inject a second intravenously to fight leukemia.

She picked up vincristine, which was supposed to be used intravenously, and injected it into Michael's

Virginia to be near her husband. She left ____ two weeks ago and now works at Georgetown University Hospital in Washington, D.C.

Michael's parents are angry and want Reilly's license revoked.

"I think Michael deserves a little bit of his justice," said the boy's father, Leon Sozookie, a legal assistant with the state Agriculture Department.

The state Board of Osteopathic Medicine, which licenses and regulates osteopathic physicians such as Reilly, was not notified about the accident. By law, hospitals are required to inform the board only if they discipline a doctor.

FDA updates vinca alkaloid labeling for preparation in intravenous infusion bags only

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[4/21/22] FDA worked with drug application holders to remove instructions for preparation of vinca alkaloids by syringe and to recommend preparation in intravenous infusion bags only. These labeling updates are complete, and the updated prescribing information for vinca alkaloids now contains instructions for health care professionals to only prepare these drugs in intravenous infusion bags.

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August 05, 2022

IMPORTANT PRESCRIBING AND DISPENSING INFORMATION

Subject: Minimizing wrong dose medication errors and revised Patients, Parents and Caregivers Fact Sheet for PAXLOVID (nirmatrelvir tablets; ritonavir tablets).

Dear Healthcare Provider,

FDA alerts health care professionals of compatibility issues with prefilled glass syringes and certain Luer-activated valve (LAV) connectors

Share Tweet Linkedin Email Print

[11/22/2022] FDA is alerting health care professionals that certain Luer-activated valve (LAV) connectors (sometimes referred to as needleless Luer access devices or needleless connectors) with internal pin designs may not be compatible with prefilled glass syringes (e.g., naloxone prefilled glass syringes). The internal pin of the LAV connector may

United States Pharmacopeia General Chapter <7>

<7> LABELING

INTRODUCTION

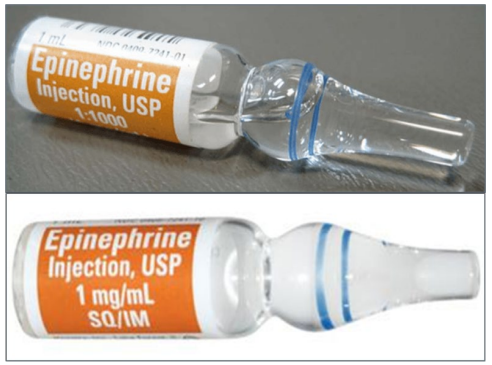
This general chapter provides definitions and standards for labeling of official articles. Labeling standards for an article recognized in *USP–NF* are expressed in the article's monograph and applicable general chapters. It is intended that all articles in *USP* or *NF* will be subject to the labeling requirements specified in this chapter by means of a provision in *General Notices, 10 Preservation, Packaging, Storage, and Labeling*, unless different requirements are provided in a specific monograph. As with compendial standards for naming, identity, strength, quality, and purity, compendial requirements for labeling have a role in the adulteration and misbranding provisions of federal law [see the Federal Food, Drug, and Cosmetic Act (FDCA) sections 501(b), 502(e)(3)(b), 502(g), and 502(h)]. Exceptions or additional requirements specific to animal drug products and compounded preparations are provided in separate sections. Vaccine labeling is not included in this general chapter.

DEFINITIONS

The term "labeling" includes all labels and other written, printed, or graphic matter on an article's immediate container or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" is that part of the labeling on the immediate container.

A shipping container that contains a single article, unless the container also is essentially the immediate container or the outside of the consumer package, must be labeled with a minimum of product identification (except for controlled substances), lot number, expiration date, and conditions for storage and distribution.

Beyond-use dates (BUDs) and expiration dates are not the same. An expiration date identifies the time during which a conventionally manufactured product, active ingredient, or excipient can be expected to meet the requirements of a compendial monograph, if one exists, provided it is kept under the prescribed storage conditions. The expiration date limits the time during which the conventionally manufactured product, active pharmaceutical ingredient (API),



- Metric units
- Use of leading and terminal zeros
- Abbreviations of the word, "units"
- Quantity and total volume expression
- Ratio expressions
- Potassium chloride concentrate labeling
- Neuromuscular blocker labeling
- Expiration date labeling

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The Joint Commission

- Elimination of “Rule of 6” for pediatric IV infusions
- Unsafe or do not use medical abbreviations
- Tall man (mixed case) lettering for look-alike drug names (**EPINEPH**rine - e**PHED**rine)
- Storage restrictions of concentrated potassium chloride implemented via NPSGs
- High-alert medications

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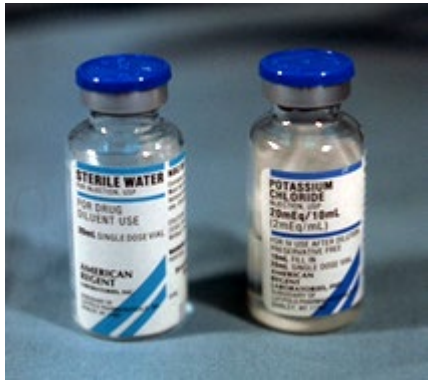

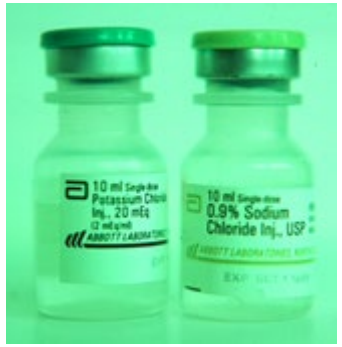

CHARLOTTE OBSERVER
APR 90

Potassium Kills Baby At Center

Associated Press

DURHAM — A premature baby has died at niversity Medical Center after receiving too much supplemental potassium, representatives said.

The infant, a twin born at 26 weeks, died about 11 days ago, said Andrew Wallace, the medical center's vice president for health affairs. The surviving twin was at the last time he checked, he said, but hospital officials would not confirm that the twin was still there this weekend.

The baby died after receiving an infusion "to correct an imbalance of electrolytes," Wallace said.

An effort was being made to increase the baby's amount of potassium. Potassium, a major element of fluid inside cells, helps regulate several body functions.

Wallace said no wrongdoing had been found involving doctors or nurses. He said the medical center had changed its procedures as a result, but would not elaborate.

"The individuals involved are

lar occurrence in the future."

The statement was released after an anonymous caller reported the death to WTVD (channel 11) in Durham.

An autopsy was performed, Wallace said. But results aren't available yet.

neonatal intensive care unit is one of about 20 in the state. Roughly half of the babies treated come from other hospitals, but Wallace said he did not know if the twins were born at

He declined to identify the baby or say where the family lives.

The Joint Commission

Sentinel Event Alert

Issue 1 - February 28, 1998

New Publication

We are pleased to introduce the first issue of Sentinel Event Alert, a periodic publication dedicated to providing important information relating to the occurrence and management of sentinel events in Joint Commission-accredited health care organizations. Sentinel Event Alert, to be published when appropriate as suggested by trend data, will provide ongoing communication regarding the Joint Commission's Sentinel Event Policy and Procedures, and most importantly, information about sentinel event prevention. It is our expectation and belief that in sharing information regarding the occurrence of sentinel events, we can ultimately reduce the frequency of medical errors and other adverse events.

Initially, Sentinel Event Alert will be mailed to the organization chief executive officers and Joint Commission survey coordinators, however, it is expected that eventually Sentinel Event Alert will be sent via broadcast fax. In the future, staff from the Joint Commission will be contacting your organization to collect appropriate fax and E-mail addresses.

While the topic of this first issue is particularly relevant to acute care facilities, we will share information of relevance to all accredited organizations in future issues.

"The way to prevent tragic deaths from accidental intravenous injection of concentrated KCl is excruciatingly simple -- organizations must take it off the floor stock of all units. It is one of the best examples I know of a 'forcing function' -- a procedure that makes a certain type of error impossible."

Lucian L. Leape, M.D. Harvard School of Public Health

Medication Error Prevention -- Potassium Chloride

In the two years since the Joint Commission enacted its Sentinel Event Policy, the Accreditation Committee of the Board of Commissioners has reviewed more than 200 sentinel events. The most common category of sentinel events was medication errors, and of those, the most frequently implicated drug was potassium chloride (KCl). The Joint Commission has reviewed 10 incidents of patient death resulting from misadministration of KCl, eight of which were the result of direct infusion of concentrated KCl. In all cases, a contributing factor identified was the availability of concentrated KCl on the nursing unit. In six of the eight cases, the KCl was mistaken for some other medication, primarily due to similarities in packaging and labeling. Most often, KCl was mistaken for sodium chloride, heparin or furosemide (Lasix).

Issue For Consideration

In light of this experience, the Joint Commission suggests that health care organizations NOT make concentrated KCl available outside of the pharmacy unless appropriate specific safeguards are in place.

"Unfortunately, there are too many in health care who feel that if it hasn't happened to them, the adverse experiences of others do not apply. That is why potassium chloride concentrate vials can still be found in patient care areas."

Michael Cohen, MS, FASHP, President, Institute for Safe Medication Practices

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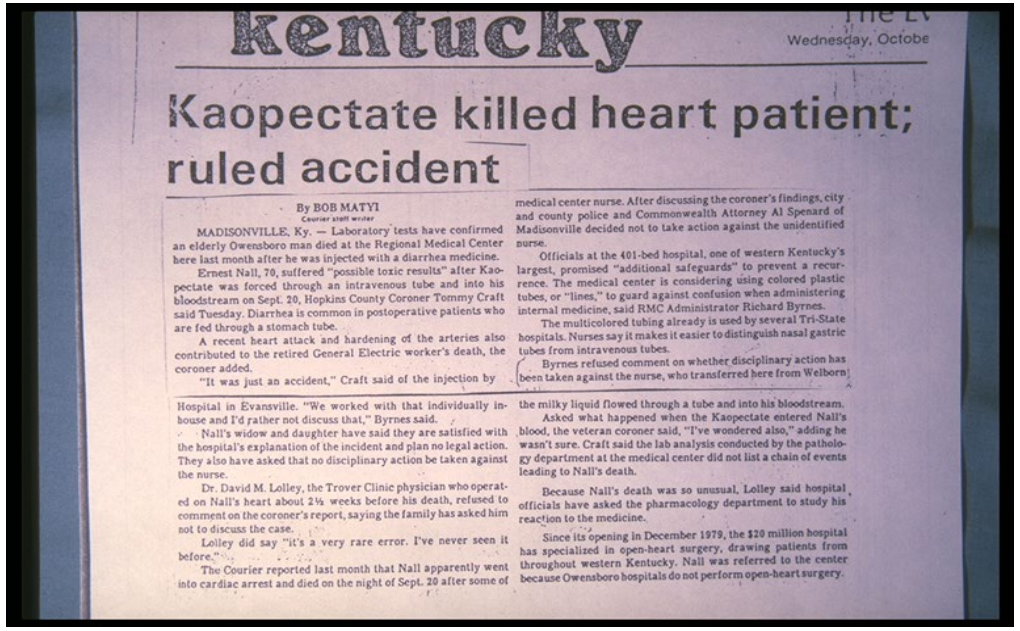
Preventing Catheter and Tubing Misconnections



Kentucky

Wednesday, Octobe

Kaopectate killed heart patient; ruled accident

By BOB MATYI
Courier staff writer

MADISONVILLE, Ky. — Laboratory tests have confirmed an elderly Owensboro man died at the Regional Medical Center here last month after he was injected with a diarrhea medicine.

Ernest Nall, 79, suffered "possible toxic results" after Kaopectate was forced through an intravenous tube and into his bloodstream on Sept. 20, Hopkins County Coroner Tommy Craft said Tuesday. Diarrhea is common in postoperative patients who are fed through a stomach tube.

A recent heart attack and hardening of the arteries also contributed to the retired General Electric worker's death, the coroner added.

"It was just an accident," Craft said of the injection by medical center nurse. After discussing the coroner's findings, city and county police and Commonwealth Attorney Al Spenard of Madisonville decided not to take action against the unidentified nurse.

Officials at the 401-bed hospital, one of western Kentucky's largest, promised "additional safeguards" to prevent a recurrence. The medical center is considering using colored plastic tubes, or "lines," to guard against confusion when administering internal medicine, said RMC Administrator Richard Byrnes.

The multicolored tubing already is used by several Tri-State hospitals. Nurses say it makes it easier to distinguish nasal gastric tubes from intravenous tubes.

Byrnes refused comment on whether disciplinary action has been taken against the nurse, who transferred here from Welborn Hospital in Evansville. "We worked with that individually in-house and I'd rather not discuss that," Byrnes said.

Nall's widow and daughter have said they are satisfied with the hospital's explanation of the incident and plan no legal action. They also have asked that no disciplinary action be taken against the nurse.

Dr. David M. Lolley, the Trover Clinic physician who operated on Nall's heart about 2½ weeks before his death, refused to comment on the coroner's report, saying the family has asked him not to discuss the case.

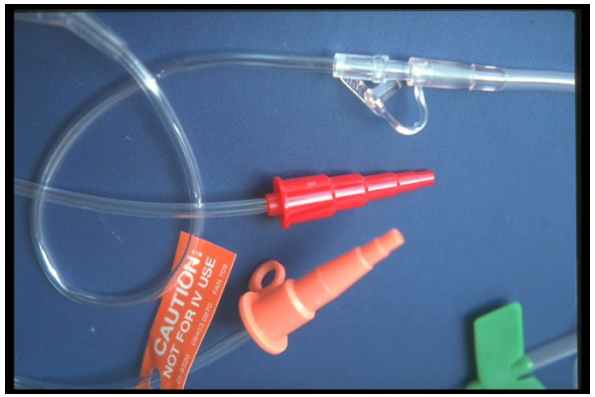
Lolley did say "it's a very rare error. I've never seen it before."

The Courier reported last month that Nall apparently went into cardiac arrest and died on the night of Sept. 20 after some of the milky liquid flowed through a tube and into his bloodstream.

Asked what happened when the Kaopectate entered Nall's blood, the veteran coroner said, "I've wondered also," adding he wasn't sure. Craft said the lab analysis conducted by the pathology department at the medical center did not list a chain of events leading to Nall's death.

Because Nall's death was so unusual, Lolley said hospital officials have asked the pharmacology department to study his reaction to the medicine.

Since its opening in December 1979, the $20 million hospital has specialized in open-heart surgery, drawing patients from throughout western Kentucky. Nall was referred to the center because Owensboro hospitals do not perform open-heart surgery.



New ENFit pump set connector Design (replaces stepped connector) – gender is female

New ENFit feeding port design – gender is male

Tylenol

- Influenced manufacturer recall due to confusing labels (2005)
- Removal of concentrated acetaminophen 100 mg/mL in pint bottles from market (2008)
- FDA safety alert on infant acetaminophen concentration (2011)
- Removal of 100 mg/mL drops from market

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Labeling Changes

- Multiple mix-ups reported between Prolia and Udenyca prefilled syringes.
- Each packaged in similar green and white cartons, with the concentration listed in a green circle in the same location.
- Both products stocked in oncology and infusion centers, are refrigerated, and may be stored near each other.

ISMP Medication Safety Alert! 2019;24(17):1-2.
ISMP Medication Safety Alert! 2020;25(2):4.

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Questions?