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ISMP An ECRI Affiliate

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Updated guidance needed for longstanding LVP labeling and packaging problems

Problem: ISMP has received ongoing reports of confusion and errors associated with the labeling and packaging of large volume parenterals (LVPs). LVPs are premixed solutions of more than 100 mL that are provided in ready-to-infuse dosage forms. These premixed solutions reduce the potential for compounding errors and provide a sterile end product that is labeled with the ingredients and a barcode. However, errors associated with the labeling and packaging of LVPs have occurred for decades. Concerns that frequently arise in the error reports submitted to ISMP include the similar appearance of containers, problems with barcodes, and label clutter.

In January 2007, the US Food and Drug Administration (FDA) held a 1-day public meeting with representatives from ISMP and USP to explore how the labels on intravenous (IV) products could be designed to minimize medication errors, including the placement, style, and type of information required on LVP labels (www.ismp.org/ext/639). The findings from that meeting led to the publication of the April 2013 FDA Draft Guidance for Industry, *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (www.ismp.org/ext/473). This Draft Guidance, which has not been finalized yet, includes a section on labels for LVPs that describes information FDA considers essential versus clutter on the LVP labels (lines 658-708). Nevertheless, the labels on LVPs continue to contribute to errors, which involve products from most of the major manufacturers in the US, including B. Braun, Baxter, Hospira, Fresenius Kabi, and ICU Medical. Most of the reports submitted to ISMP involve soft bag LVPs, which comprise a majority of the US market (compared to glass or plastic bottle LVPs).

Similar Appearance of Containers

The most frequent contributing factor associated with LVP error reports received by ISMP is the inability to distinguish different products, including different strengths of drug products, due to look-alike packaging and labeling. Most LVPs are available in an overwrap which can make the labels even more difficult to read and distinguish from each other.

Differing strengths. In the past 5 years, ISMP has received numerous reports of look-alike LVPs containing different strengths of the same drug. For example, both Hospira's and Baxter's look-alike bags of **DOBUT**amine 1,000 mg/250 mL have been repeatedly mixed up with the 250 mg/250 mL strength. Also, both manufacturers' **DOP**amine 800 mg/250 mL infusions have been mixed up with look-alike containers of 200 mg/250 mL (Baxter) and 400 mg/250 mL (Hospira, **Figure 1**) strengths. All of these products are packaged in foil or opaque overwraps to protect the drugs from light and

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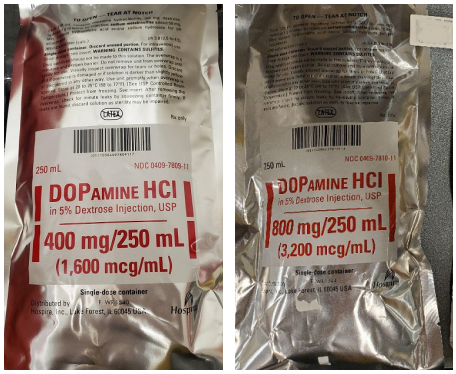

Figure 1. Label confusion reported in 2020 between look-alike containers of Hospira's **DOP**amine 400 mg/250 mL (left) and 800 mg/250 mL (right).

ISMP comments on **cisatracurium mislabeling and recall** — see **page 5.**

SAFETY briefs

Dosing error with Entresto. A dispensing error occurred when a pharmacist misinterpreted a prescription for **ENTRESTO**, a product used to treat heart failure that contains sacubitril and valsartan in different amounts (i.e., 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg). The prescription listed the strength as 100 mg, which the patient was supposed to take twice daily. However, none of the three available strengths of Entresto includes a 100 mg strength. The pharmacist dispensed what he thought was closest to the strength prescribed, the 97 mg/103 mg product, and instructed the patient to take the medication twice daily.

A few months later, the patient's physician increased the dose to 200 mg twice daily, and the pharmacist dispensed the 97 mg/103 mg strength with instructions to take 2 tablets twice daily. However, that dose soon led the patient to experience severe side effects, including intense lethargy and hypotension. At that point, the pharmacist discovered the patient had received twice the intended dose due to a dispensing error. The prescriber had added the dosage amounts of the two ingredients together in the original prescription, so Entresto 49 mg/51 mg (100 mg total) was the original intended dose (**Figure 1**). Even though the

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Figure 1. A pharmacist dispensed Entresto 97 mg/103 mg (top), thinking the strengths were closest to the 100 mg strength prescribed. However, the prescriber intended for the patient to receive the 49 mg/51 mg strength (49 + 51 = 100) (bottom).

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prevent evaporation of the solution, adding to their similar appearance. Strength mix-ups of these inotropic medications could have an adverse clinical impact on the patient's blood pressure, heart rate, and cardiac output.

Various strengths of heparin have also been confused due to look-alike labeling and packaging, including B. Braun's heparin 25,000 units/500 mL and 20,000 units/500 mL, as well as heparin 1,000 units/500 mL (intended for arterial lines) and 25,000 units/500 mL. Mix-ups in heparin concentrations could result in ineffective anticoagulation from subtherapeutic doses or bleeding from overdoses.

Differing base solutions. The design of LVP labels and look-alike similarities can make it difficult to distinguish the base solutions used for similar products. For example, we recently received reports—one at the end of 2020 and one early in 2021—involving mix-ups between Baxter's premixed 1-liter bags containing potassium chloride in differing base solutions. These products are marketed in several strengths (10 mEq/L, 20 mEq/L, 30 mEq/L, 40 mEq/L) and in several base solutions (5% dextrose in water [D5W], 0.45% sodium chloride, 0.9% sodium chloride, D5W and lactated ringer's, D5W and 0.2% sodium chloride). All of these products look similar, with the strength and potassium chloride in large red letters at the top of the bag and the base solution listed in much smaller red print below the drug name (**Figure 2**), increasing the risk, for example, that 0.45% sodium chloride with 20 mEq of potassium chloride is inadvertently administered instead of D5W/0.45% sodium chloride with 20 mEq of potassium chloride. The similar-looking bags could easily be stored near each other since they all contain the same amount of potassium chloride per liter. The difference in base solutions may seem insignificant but could impact a variety of patients such as those with electrolyte imbalances and specific fluid requirements or restrictions.

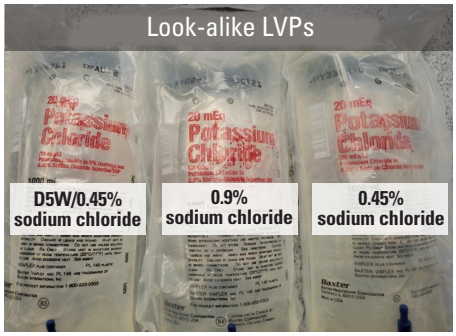

Figure 2. Baxter's potassium chloride infusions have almost identical product labeling; they all contain the same amount of potassium chloride (20 mEq/1,000 mL) but have different base solutions (as captioned on each bag).

Healthcare practitioners have also commented on the red print used for labeling these solutions given that the color "red" is the traditional color of "warning" and "danger." They argue that, because one of the most common infusions administered today is labeled using red print, practitioners have become desensitized and are less likely to notice the red print intended to draw attention to a bag of sterile water for injection, for example.

Figure 3. B. Braun's 500 mL bags of 3% sodium chloride (left) and 25,000 units of heparin (right) look very similar in their overwraps.

Differing products. ISMP has also received dozens of error reports in the past 5 years associated with look-alike LVP bags containing different drugs. Mix-ups that have caused patient harm or could result in serious harm include confusion between B. Braun's look-alike 500 mL bags of heparin and lidocaine, heparin and **HESPAN** (hetastarch), heparin and sterile water for injection, and heparin and 3% sodium chloride (**Figure 3**).

Problems with Barcodes

ISMP has received numerous reports about the inability to scan the manufacturer's barcode on LVPs. The most frequent concern is difficulty scanning a white barcode printed

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Dr. Allen Vaida retiring, Dr. Rita Jew joins staff

ISMP has announced that Executive Vice President **Allen Vaida, PharmD, FASHP**, will be retiring at the end of March 2021. Dr. Vaida has been an integral part of the ISMP team for decades and has had an immense impact on patient safety, the practice of health-system pharmacy, and ISMP. He has been ISMP's representative on numerous committees and influential healthcare groups, including the inaugural USP Safe Medication Use Expert Committee, US Food and Drug Administration (FDA) committees on risk management and pharmacy compounding, and the Accreditation Council for Graduate Medical Education's Patient Safety Task Force. He has worked with healthcare accrediting bodies, regulators, and professional organizations both nationally and internationally, and has given presentations on medication safety around the world.

"Allen has been an invaluable asset," says ISMP President Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP. "He will be sorely missed for his vision, collaborative spirit, and integrity. He has helped ISMP build a reputation as the gold standard for medication safety information and served as a mentor and role model for countless healthcare professionals."

Dr. Vaida will be succeeded by **Rita Jew, PharmD, MBA, BCPPS, FASHP**, as ISMP's new Vice President of Operations. Dr. Jew has an MBA from the Wharton School of the University of Pennsylvania and is a nationally recognized pharmacy executive and expert in hospital technology, medication management strategy, and operations. She was most recently a principal in her consulting practice and, prior to that, she held leadership positions at several well known acute care institutions, including University of California San Francisco (UCSF) Health, Children's Hospital of Orange County, and Children's Hospital of Philadelphia. Dr. Jew has received numerous awards, including a Distinguished Service Award from the American Society of Health-System Pharmacists (ASHP) Section of Clinical Specialists and Scientists. Please join us in welcoming Rita to ISMP (info@ismp.org)!

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on a clear LVP bag, which has been reported with Baxter, B. Braun, Hospira, and Fresenius Kabi (**Figure 4**) LVPs. Reporters note that the white barcodes are especially difficult to scan when the clear soft plastic infusion bags are upright, as hanging on an IV pole, and are easier to scan when held against a dark background, such as laying the bag on a dark table. Occasionally, we also hear about scanning difficulties with black barcodes on clear bags due to barcode quality issues, or scanning difficulties associated with the position of the barcode on the bag.

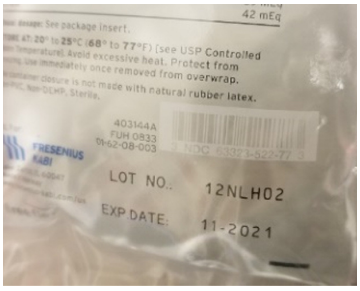

Figure 4. Fresenius Kabi's heparin 25,000 units in 500 mL of D5W has a white barcode on the clear bag, making it nearly impossible to scan.

Another problem is the absence of a barcode on the overwrap itself. As above, most LVPs are packaged in an overwrap to prevent evaporation and to maintain sterility and stability and are dispensed to patient care units in an overwrap. However, while manufacturers include a barcode on the actual LVP container, they may not print a barcode on the overwrap. Without a barcode on the overwrap, pharmacy staff may not be able to scan the barcode to verify the drug prior to dispensing or stocking the LVP. Scanning the barcode through a clear overwrap may be possible with some LVPs, but it is nearly impossible with some B. Braun LVPs in clear overwraps if the overwrap seam runs through the barcode (an issue that was corrected with some LVPs but not with others).

The printing of dual barcodes on the actual LVP container—one to aid the manufacturing process and the other for healthcare providers to scan—is another problem, one that appears to be unique to B. Braun LVPs. Healthcare providers have scanned the wrong barcode without success, leading to omissions and overrides of the scanning technology.

Label Clutter

The large amount of information that typically appears on the LVP label not only clutters the label but can also distract from the most important information—the product name, main ingredients, and the strength. As an example see **Figure 5**, which depicts a label for a plain solution containing 0.9% sodium chloride from ICU Medical. Most of the information below the product name and strength makes the label look crowded. This label, which is typical for LVPs, contains extra information that the 2013 FDA Draft Guidance for Industry (www.ismp.org/ext/473, lines 685-708) lists as "label clutter" and should NOT be included:

- A statement that the product is "non-pyrogenic"
- A statement about the pH
- A statement to "use only if solution is clear and container is undamaged"
- A statement about "series connection"
- Manufacturer's address

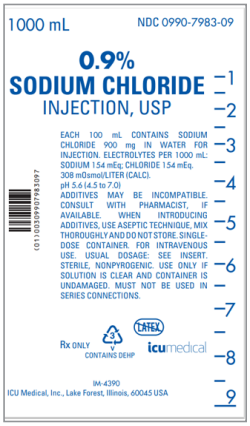

Figure 5. Label on ICU Medical's 1,000 mL bag of 0.9% sodium chloride injection contains required information as well as label clutter in smaller print below the product name and strength.

Although some of the following statements may have been deemed essential for the container label per the 2013 FDA Draft Guidance for Industry (lines 663-683), ISMP questions the importance of including these on LVP labels, as they contribute to label clutter:

- "Each 100 mL contains…." (this statement has also been misinterpreted as the total amount in an LVP when the LPV contains more than 100 mL)
- A statement to "see prescribing information" (or insert)
- A statement, "additive compatibility, consult pharmacist" or "additives may be incompatible, consult with a pharmacist, if available"
- A statement, "when introducing additives, use aseptic technique, mix thoroughly, and do not store"

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product label lists the ingredients separately, the package insert suggests that dosing in clinical trials was based on the total amount of both components of Entresto; sacubitril and valsartan 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg were referred to as 50 mg, 100 mg, and 200 mg, respectively. Also, instructions for preparing a suspension from eight 49 mg/51 mg tablets indicates the final concentration in terms of the combined strengths of the ingredients, 800 mg/200 mL.

Such confusion by the pharmacist is easy to understand. A few combination products are labeled with the strength expressed as the total dose after combining the component drug doses together—**ZOSYN** (piperacillin and tazobactam) is one example (e.g., strength expressed as 4.5 g, which includes piperacillin 4 g and tazobactam 0.5 g). However, most combination tablets in the US are prescribed according to the strengths of each respective drug, not the total strength of all active ingredients. For example, the anti-Parkinson's drug **SINEMET** (carbidopa and levodopa) lists the ingredients separately on the label and in the package insert, and the drug is prescribed according to the strengths of each respective drug (i.e., Sinemet 10 mg/100 mg, Sinemet 25 mg/100 mg), not the combined total of both drugs. Entresto product labeling mentions dosing both in terms of individual ingredient strengths as well as the total mg dose of the two ingredients added together. Ideally, the way strengths are expressed for multi-ingredient products and how these drugs are prescribed should be standardized to prevent confusion. For now, please inform both prescribers and pharmacy staff about this potential for error. An alert in both prescribing and dispensing software should be considered until a change occurs in the way the product is labeled.

HIGH-ALERT

Syringes with trailing zeros. A pharmacist was completing a medication history and education session with a patient who used injectable methotrexate for psoriasis. The patient stated that she draws her methotrexate injection "up to the 10" on the syringe, but she did not know the dose in milligrams. The patient was using a 25 mg/mL injectable product, so 10 mL (250 mg) would have been too high of a dose for psoriasis, which is typically 10 to 25 mg once weekly. Upon further probing, the

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Additionally, the format and layout of the information below the product name and strength often makes it hard to read. For example, the information is often presented in all uppercase letters, which is more difficult to read than lowercase or mixed case words, and the information may not be organized into relevant sections. And once the LVP is dispensed, the information in small print below the product name and strength is often covered with a pharmacy/patient label, rendering it unreadable.

Safe Practice Recommendations: ISMP has once again reached out to FDA and several LVP companies in the US to discuss these ongoing risks and errors and to recommend label improvements to better distinguish LVPs and improve the readability of their labels. These companies agreed to explore the much-needed label improvements to promote medication safety. ISMP is also calling upon FDA to update and finalize its guidance to manufacturers regarding the labels for LVPs, taking into consideration the ongoing nature of reported errors associated with look-alike containers, problems with barcodes, and label clutter. ISMP encourages collaboration among FDA, USP, LVP manufacturers, ISMP, and other safety experts to expand and update the current regulatory guidance for the labeling of LVPs. Specifically, we recommend the following:

- Label redesign, including style, font type, and the limited use of color, to better distinguish between different products, different base solutions, and different strengths
- Label placement on both the front and back of LVPs containing ISMP-designated high-alert medications, with the text not overlapping other text and readable in both the upright and inverted positions, leaving space below the product name and strength for a pharmacy/patient label
- Reconsideration of the information deemed "essential" for the container label, which could appear instead in the prescribing information, to further reduce label clutter (this will likely require difficult regulatory changes)
- Requiring segmentation of any "essential" information required on the label below the product name and strength into relevant categories (e.g., storage, route of administration)
- Requiring the placement of a two-dimensional (2D) barcode (using dark black lines on an opaque white background for all barcodes) on both sides of the actual LVP container as well as the overwrap, unless at least one barcode on the actual LVP is machine readable through a clear overwrap, without a crimp from the overwrap running through the barcode (FDA currently requires a barcode on the overwrap [www.ismp.org/ext/266, see question/answer #14]; however, this requirement is not always followed)

Meanwhile, healthcare practitioners can reduce the risk of errors by identifying look-alike LVPs prone to mix-ups, separating their storage, clearly labeling storage locations, and affixing unique labels to the few products with the most potentially serious outcomes to help identify and distinguish the products, base solutions, and/or strengths. A pharmacy and therapeutics committee should consider whether all sizes and strengths of LVPs are necessary, and then limit the variety of LVPs by removing those with limited use or value from certain storage locations or from the hospital inventory.

Although it may be challenging in some instances, consistent use of barcode scanning will help minimize the potential for errors with these products. Practitioners should be reminded that the barcode on the actual LVP, not a barcode on the overwrap, should be scanned immediately prior to administration. Scanning the barcode on the overwrap would be similar to scanning a carton containing a vial of medication, instead of the actual medication vial. Consider monitoring scanning practices to ensure practitioners are adhering to this important safety measure.

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patient confirmed that she draws the medication "up to the little 10." The pharmacist considered the possibility that the patient had been using an insulin syringe, as this is the only type of small syringe that has markings for whole numbers including a "10." This was also concerning. If the patient had been withdrawing methotrexate up to the "10 units" mark on an insulin syringe, this would have been only 0.1 mL (2.5 mg) of methotrexate, which would have been an underdose. The pharmacist contacted the dispensing pharmacy, which confirmed that they had dispensed tuberculin (TB) syringes to the patient. The pharmacist noticed online that some TB syringe scales use a trailing zero after the decimal point (i.e., 1.0 for 1 mL), and a few even failed to include a leading zero before a decimal point (e.g., .1, .2, .3) (**Figure 1**).

Figure 1. TB syringe with error-prone measurement marks that do not include a leading zero (e.g., .2, .3) and include a dangerous trailing zero (i.e., 1.0).

Fortunately, this patient had been drawing up the correct 1 mL amount (25 mg) but thought she was drawing the medication up to the "10," as she did not see the decimal point in the "1.0" syringe marking. This could have resulted in a serious medication error if the pharmacist had entered "10 mL" into the patient's health record during medication reconciliation, or if the patient had indeed been taking the wrong dose based on confusion with the markings on the syringe. The pharmacist was able to counsel the patient regarding the correct dose. The ISMP National Medication Errors Reporting Program (ISMP MERP) has a long history of receiving error reports involving trailing zeros and lack of a leading zero. For decades, ISMP has recommended avoiding trailing zeros and including leading zeros for decimal doses, and we recently began repeating this recommendation to various manufacturers in reference to their syringes.

Cisatracurium mislabeling incident calls for more efficient ways to alert the field

A recent recall of Meitheal Pharmaceuticals' cisatracurium vials mislabeled as phenylephrine took almost a week from when the problem was first noticed until recall notices from the US Food and Drug Administration (FDA) and the manufacturer began appearing in email inboxes nationally. A pharmacist from MercyOne Siouxland Medical Center in Sioux City, Iowa, first discovered the mislabeled vials on January 24, 2021. She found 5 cartons out of 22, all with the same C11507A lot number, that were labeled cisatracurium 10 mg/5 mL but actually contained vials labeled phenylephrine 100 mg/10 mL (**Figure 1**). The "phenylephrine" vials had light blue caps with "Warning: Paralyzing Agent" printed on them, while the other cartons contained vials labeled as cisatracurium with the same light blue caps. That led the pharmacist to suspect the phenylephrine vials were mislabeled. Although it was a Sunday, she immediately alerted the FDA via a 24-hour emergency number (1-866-300-4374) but was advised to call a regional office, where she had to leave a voicemail message. She attempted to contact Meitheal, but the company had no call center, voicemail, or email system that was operational on Sunday. The pharmacist also tried to alert the hospital's distributor, AmerisourceBergen, but again, the distributor did not have voicemail operational on Sunday, so the pharmacist sent an email message instead (which was returned more than a week later).

The pharmacist called Meitheal again on Monday morning, left a message on voicemail, and received a return phone call later that afternoon. During that call, the pharmacist was surprised to learn from Meitheal that she was not the first person who had found what appeared to be mislabeled vials. Meitheal told the pharmacist that another hospital had notified the manufacturer about the same problem 3 days earlier on Friday, January 22, 2021. A pharmacy manager at MercyOne Siouxland submitted an error report to ISMP and FDA on late Monday afternoon. ISMP processed the error the following morning on Tuesday, bringing it to the attention of ISMP staff. The medication safety officer at Mount Carmel Health System in Columbus, Ohio, also alerted us to the hazard that day through a posting on the Medication Safety Officers Society website, which ISMP operates.

This situation was exceptionally concerning. If a patient who was not intubated required phenylephrine and received cisatracurium due to the mislabeling, the consequences would be severe. Due to a high risk for a harmful outcome, ISMP decided to issue a national alert on Tuesday evening, January 26, 2021, rather than wait for that week's *ISMP Medication Safety Alert!* publication or take additional time to activate the National Alert Network (NAN) Alert in cooperation with the American Society of Health-System Pharmacists (ASHP). ISMP also contacted FDA and confirmed that the event had been reported to the recall office. When we tried to contact Meitheal, no one answered the phone and a voicemail message was left. The call was returned the following day.

Unfortunately, recall alerts (www.ismp.org/ext/641) from FDA and Meitheal did not reach our email until Thursday, January 28, 2021, nearly a week after the mix-up was first reported to the manufacturer. And the alerts were confusing, detailing not only what could happen if a patient accidentally received cisatracurium, but also what could happen if a patient received phenylephrine when cisatracurium was needed. This could have led to a misunderstanding that phenylephrine, rather than cisatracurium, was in the vials.

As far as we know, no adverse outcomes resulted from the mislabeled vials. However, this event calls for improvement in how urgent events are communicated so they can lead to more timely recall notices and follow-up. Pharmaceutical companies should be required to maintain emergency phone numbers that reach an on-call person or answering service that can quickly relay messages. Also, the company should react to urgent situations quickly—depending on severity, even within 24 hours, including on weekends. While an investigation takes time, an emergency notification may be in order. In this case, a week's delay could have easily resulted in patient deaths. We wonder if there have been other serious events that took almost a week before FDA and the manufacturer issued an alert.

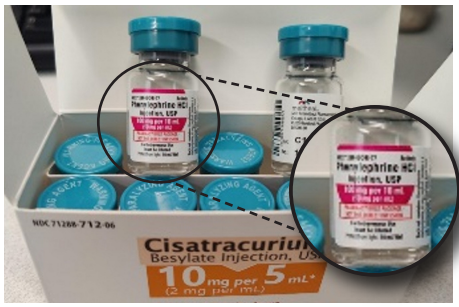

Figure 1. Carton labeled properly as cisatracurium; however, the vials which contain cisatracurium are mislabeled as phenylephrine.

Special Announcement

ISMP's updated list of error-prone abbreviations now on our website

We recently posted our updated ***ISMP List of Error-Prone Abbreviations, Symbols, and Dose Designations***, which can be accessed at: www.ismp.org/node/8. These abbreviations, symbols, and dose designations have been misinterpreted and involved in harmful or potentially harmful errors—they should **NEVER** be used in verbal, handwritten, and/or electronic communication. Please review ISMP's updated list to see if your organization's "**Do Not Use**" list requires updating. ISMP's list points out the error-prone abbreviations, symbols, and dose expressions included on The Joint Commission's "**Do Not Use**" list, which must be included on an accredited organization's "**Do Not Use**" list.

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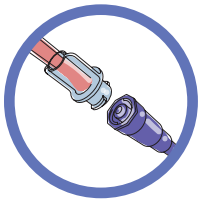
WINTER 2021

ISMP Resources and Services



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Prevent enteral-route misconnections by adopting ENFit-compliant devices in your organization! Learn how ENFit can reduce the risk of enteral-to-IV misconnections during a free ISMP webinar on February 24, 2021, from 1:00-2:00 p.m. ET (**CE available**).

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