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ISMP Institute for Safe Medication Practices
An ECRI Company

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Judicious Use of Auxiliary Labels for Medication Containers Requires a Systematic Approach

Problem: An auxiliary label is a small, often brightly colored, adhesive sticker placed on a drug container or added to the pharmacy-prepared label by a pharmacy technician or pharmacist to highlight critical safety warnings, storage requirements, or administration instructions that may or may not be found on the medication label.[1,2] Although the intent behind using auxiliary labels is to enhance medication safety, they can contribute to downstream problems that may not be identified until after an error occurs.[2] Additionally, during consulting engagements, ISMP has found that some healthcare practitioners exhibit a sense of overreliance on these labels as the source of truth rather than reviewing the information provided on the medication administration record (MAR) and the manufacturer or pharmacy-prepared label. Therefore, auxiliary labels sometimes provide a false sense of security. Without technology to generate these warnings, the process of adding appropriate, meaningful auxiliary labels is left to humans, increasing the risk of adding an incorrect auxiliary label or omitting one altogether. Or, depending on how they are affixed, labels can detach and adhere to other products.

Additional concerns include the risk of alert fatigue if the pharmacy adds auxiliary labels to the majority of medications or sticks multiple warning labels on a single medication container.[2] Other times, the information on the label is vague, simply stating the drug name or route that is already on the medication label, or includes a general warning such as "look-alike," "high-alert," or "continuous IV drip" without stating a clear action for the end user. Other risks include auxiliary labels with negative warnings such as "NOT FOR PARENTERAL USE."[2,3] The concern with negative warning statements is that the practitioner may only see the active action and miss the "NOT" in the beginning part of the statement, especially if the product container is turned, the label is folded/obstructed, or the statement is separated on to two lines.[3]

We have also observed what appears to be a risk of overreliance on auxiliary label colors, or that color choices could contribute to mix-ups, as with look-alike medication labeling and packaging errors. One organization told us that their auxiliary label supplier had changed colors without notifying the pharmacy, and that there was no review process when the labels were delivered to assess these unforeseen changes and educate staff. Another told us that any staff member could request a new auxiliary label from the pharmacy purchaser, without a formal approval process.

Errors Reported to ISMP

*A nurse contacted a pharmacist regarding a recently delivered sodium bicarbonate infusion. The nurse reported that the bag was dispensed with an auxiliary label stating, "FOR EPIDURAL ADMINISTRATION ONLY," but the medication label stated the route was for continuous intravenous (IV) infusion. The pharmacist instructed the nurse to discard the bag and dispensed a replacement infusion. Administering an IV sodium bicarbonate infusion via the epidural route could have had catastrophic consequences for the patient, and the risk of this wrong route error may have been higher if the patient had an epidural access. During the event investigation, the pharmacy reported that there were more than 20 auxiliary labels pharmacy personnel could select from and they were stored in an unorganized manner (**Figure 1**, page 2). The label "FOR EPIDURAL ADMINISTRATION ONLY" is printed on a bright yellow sticker, the same color as the intended auxiliary label "CONTINUOUS IV DRIP, ALERT, REQUIRES RN TO DOUBLE CHECK" (**Figure 2**, page 2).*

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Your *Reports* at *Work*

Label Changes Help Differentiate Baxter Cartons and Infusion Bags. Two hospitals recently reported a look-alike concern involving Baxter's **MYXREDLIN** (insulin human) 100 units/100 mL and vasopressin 20 units/100 mL. The two products came in outer cartons that share similar label color schemes (**Figure 1**), and both are stored refrigerated. Once removed from the carton, the products were in 100 mL bags with similar-looking labeling (**Figure 2**). Because both products are high-alert medications and may be used in critically ill, high-risk populations, there was concern that the similarity could contribute to selection errors (e.g., wrong product removed from refrigerated storage or an automated dispensing cabinet [ADC] bin) and administration errors if scanning is bypassed or the barcode is scanned after administration rather than before.

Figure 1. Reporters have shared concerns that cartons of vasopressin (top) and Myxredlin (bottom) by Baxter look similar.

Figure 2. Reporters have shared concerns that bags of vasopressin (left) and Myxredlin (right) by Baxter look similar.

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Figure 1. A sample of the more than 20 auxiliary labels that can be selected for use by pharmacy personnel.

Figure 2. The intended auxiliary label (top) for the sodium bicarbonate IV infusion and the similar-looking/colored epidural label (bottom) that was selected in error.

While rounding on a patient floor, a nurse asked a pharmacist for clarification about a patient's valproic acid continuous IV infusion. The nurse explained that today, the medication came from pharmacy with an auxiliary label that had not been attached to the same medication dispensed and administered the previous day. The label read "High Alert Double Check," but the nurse noted that in the electronic health record (EHR), valproic acid does not prompt the nurse to perform a double check. The pharmacist provided an "undocumented" double check of the smart infusion pump settings but was concerned that the EHR was not set up properly. During event investigation, it was uncovered that pharmacy staff had been trained to attach the "High Alert Double Check" auxiliary label to all continuous infusions and were unaware of which medications actually required a double check per nursing policy. Additionally, valproic acid was not on the hospital's high-alert medication list, and staff assumed that this warning for "High Alert" was synonymous with "Warning" or "Caution" rather than alerting staff to a medication that was on the high-alert list.

Sharing Lessons Learned

One academic health system, the University of Kentucky HealthCare (UKHC), shared with ISMP how they addressed common pitfalls related to auxiliary labels. UKHC is a three-hospital academic health system affiliated with the University of Kentucky serving a wide patient population. The UKHC central pharmacy supports an average dispense volume of approximately 2,250 patient-specific doses per day.

Over a two-year period, the UKHC pharmacist program coordinator for medication-use safety and quality collected all auxiliary labels found in the inpatient and satellite pharmacies for evaluation. Labels were then grouped into categories: alert, route warning, production process, delivery, and storage. Initial review occurred with pharmacy leadership to identify who commonly used each label, the intended use of each label, and the rationale for the safety benefit it provides. Following pharmacy review, a refined list of labels was presented for nursing evaluation and to gather feedback. Rounding with frontline nursing staff was conducted to gather additional insight into nurses' experiences with auxiliary labels.

As a result of the review, the number of auxiliary labels was reduced from over 60 to just under 30, removing or modifying labels to ensure each has a defined expectation for use. Refer to **Table 1** for examples. One supply chain technician was designated as the primary contact to procure all labels from vendors. A standard operating procedure and auxiliary label repository were developed for pharmacy. Within the EHR, MAR icons were integrated to consistently display auxiliary warnings and important information (e.g., hazardous drug, do not crush, controlled substance designation) that might have previously relied on manual auxiliary label selection. In addition, warning labels were reviewed and adjusted where needed to keep the text visible when folded for syringe or IV tubing placement.

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Your *Reports* at *Work*

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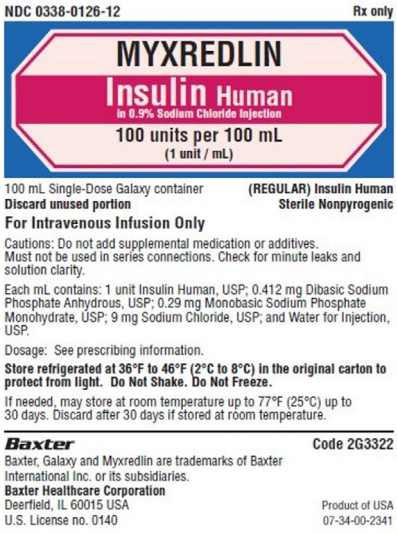
We have also warned of Myxredlin being mixed up with other Baxter products with similar-looking packaging and labeling, including in our April 4, 2024 article, Patient Found Unresponsive After Zosyn Label Placed on Myxredlin Bag Was Infused, and our May 2, 2024 article, Patient Received Myxredlin Instead of Cardene IV.

We had reached out to the US Food and Drug Administration (FDA) and Baxter and recommended differentiating the labels. We are pleased to share that Baxter updated the labels for some of their products, including Myxredlin, vasopressin, Zosyn, and Cardene, to better differentiate them. See **Figures 3**, **4**, **5**, and **6** (continued on page 3). These changes make the products appear less similar.


NDC 0338-0126-12 Rx only

MYXREDLIN
Insulin Human
in 0.9% Sodium Chloride Injection
100 units per 100 mL
(1 unit / mL)

100 mL Single-Dose Galaxy container
Discard unused portion
(REGULAR) Insulin Human
Sterile Nonpyrogenic

For Intravenous Infusion Only

Cautions: Do not add supplemental medication or additives. Must not be used in series connections. Check for minute leaks and solution clarity.

Each mL contains: 1 unit Insulin Human, USP; 0.412 mg Dibasic Sodium Phosphate Anhydrous, USP; 0.29 mg Monobasic Sodium Phosphate Monohydrate, USP; 9 mg Sodium Chloride, USP; and Water for Injection, USP.

Dosage: See prescribing information.

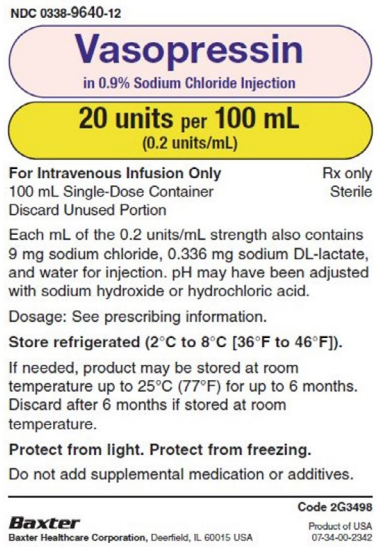
Store refrigerated at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light. Do Not Shake. Do Not Freeze.

If needed, may store at room temperature up to 77°F (25°C) up to 30 days. Discard after 30 days if stored at room temperature.

Baxter Code 2G3322

Baxter, Galaxy and Myxredlin are trademarks of Baxter International Inc. or its subsidiaries.
Baxter Healthcare Corporation
Deerfield, IL 60015 USA
U.S. License no. 0140
Product of USA
07-34-00-2341

Figure 3. Baxter's updated Myxredlin label.


NDC 0338-9640-12

Vasopressin
in 0.9% Sodium Chloride Injection
20 units per 100 mL
(0.2 units/mL)

For Intravenous Infusion Only
100 mL Single-Dose Container
Discard Unused Portion
Rx only
Sterile

Each mL of the 0.2 units/mL strength also contains 9 mg sodium chloride, 0.336 mg sodium DL-lactate, and water for injection. pH may have been adjusted with sodium hydroxide or hydrochloric acid.

Dosage: See prescribing information.

Store refrigerated (2°C to 8°C [36°F to 46°F]).

If needed, product may be stored at room temperature up to 25°C (77°F) for up to 6 months. Discard after 6 months if stored at room temperature.

Protect from light. Protect from freezing.

Do not add supplemental medication or additives.

Code 2G3498

Baxter
Baxter Healthcare Corporation, Deerfield, IL 60015 USA
Product of USA
07-34-00-2342

Figure 4. Baxter's updated vasopressin label.

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Table 1. Examples of auxiliary label review and rationale to keep or remove.

Auxiliary Label	Rationale
Caution: Chemotherapy	Remove–Duplicative, medication label includes "Hazardous Drug," and a chemotherapy bag is used for dispensing
Continuous Infusion	Remove–Duplicative, medication label includes "continuous infusion," and MAR prompts nurses to perform double check when applicable
Do Not Refrigerate	Remove–Negative statement, policy is to store medications at room temperature unless stated otherwise on medication label
Epidural	Modify–Use more descriptive language, "For Epidural Administration Only," and team to reevaluate the need for this label after NRFit has been implemented
Hand Deliver	Remove–Use "Do Not Tube" label based on feedback that nurses understand "Do Not Tube" but do not interpret "Hand Deliver" as an alert that means do not return the medication to pharmacy via pneumatic tube system
High Alert	Remove–Does not provide a specific or actionable warning, may contribute to alert fatigue and inattentional blindness
High Dose	Remove–No definition for what high dose means, not specific or actionable
Intramuscular	Remove–Duplicative, route is listed on medication label
Irrigation	Remove–Duplicative, route on medication label is more specific than simply irrigation (e.g., enema, intravesical)
Not for IV Use	Remove–Negative statement
Note Dose Strength	Remove–Does not call attention to specific behavior needing modification, medication bags with this label are thrown away, EHR alerts nurses at time of barcode administration (e.g., half a tablet, multiple tablets)
Potassium Added	Remove–Medication label and MAR include specific electrolyte name and amount
Refrigerate	Remove–Storage requirement is listed on medication label and integrated into EHR MAR icon
Subcutaneous Infusion	Modify–Use more descriptive language, "For Subcutaneous Infusion Only," low frequency of use and unfamiliarity among nursing staff could lead to a higher risk of wrong route administration
Subcutaneous Only	Remove–Easily mixed up with subcutaneous infusion, route is listed on medication label and MAR
Tubing Primed with Drug–Do NOT Flush	Keep–Blinatumomab infusion only, EHR alert cannot be integrated because no MAR action is required when infusion is complete, deviates from standard expectation to flush line
Warning: Paralyzing Agent	Modify–Use more descriptive language, "Warning: Paralyzing Agent Causes Respiratory Arrest," integrate into EHR MAR icon

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Your *Reports* at *Work*

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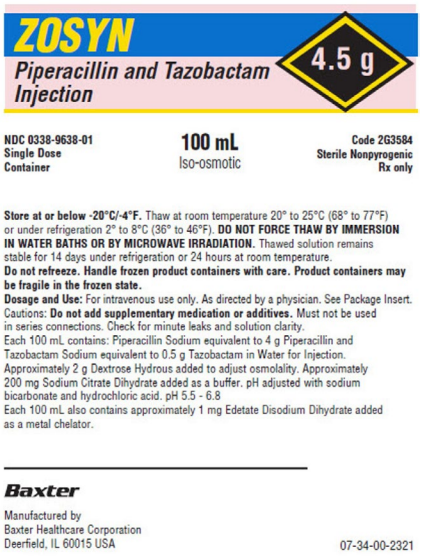

Figure 5. Baxter's updated Zosyn label.

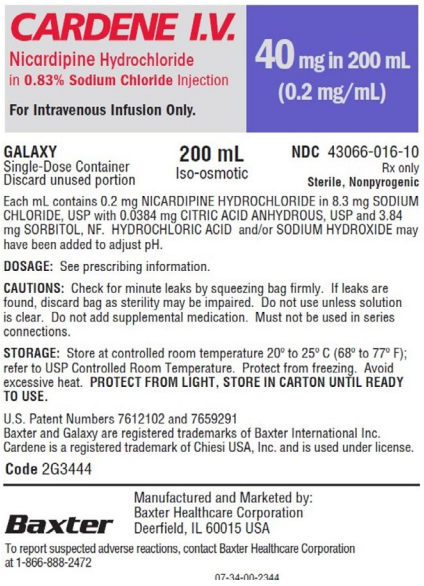

Figure 6. Baxter's updated Cardene label.

We want to thank you for reporting these issues to us. Without you, we believe these changes would not have been made. We cannot emphasize how important it is to report errors to the ISMP National Medication Errors Reporting Program (ISMP MERP) and to MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

Please keep the reports coming!

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Safe Practice Recommendations: ISMP encourages organizations to learn from UKHC's experiences with reviewing and modifying the use of auxiliary labels on medications.

Evaluate current process. Gather an interdisciplinary team (e.g., pharmacists, pharmacy technicians, nurses, anesthesiology staff, respiratory therapists) to review the workflow associated with auxiliary label use within the organization. Go to areas where the work is being done both in the pharmacy and on patient care units. Have the team conduct a failure mode and effects analysis (FMEA) to determine excessive and duplicative auxiliary labels, and the potential risks with auxiliary label use (e.g., wrong label, label omission). Additionally, assess the advantages of using auxiliary labels and clearly explain the specific safety value that the label provides. Ensure key stakeholders from different pharmacy areas (e.g., main and satellite pharmacies, sterile compounding, nonsterile compounding, supply chain, medication storage, delivery, procurement) and end users from different patient care units are included to understand the culture, needs, and potential overreliance on the use of auxiliary labels. Special consideration should be given to line labels (e.g., IV tubing labels) that nurses use, which should also be evaluated for safety risks. Understand the current process, or lack thereof, for auxiliary label approval and purchasing both within and outside of the pharmacy.

Create a policy. Create an auxiliary label policy that explicitly describes the workflow for auxiliary label use. Ideally, this policy would include a predetermined list of drugs, dispensing activities, or workflow conditions in which an auxiliary label is expected to be used. The policy should specify who is responsible for auxiliary label attachment and emphasize workflow steps to ensure consistency among all staff (e.g., exact location on the product where the auxiliary label should be placed).

Develop an approval process. The team should develop an approval process for requesting changes, additions, or deletions to auxiliary labels. Requests should be reviewed promptly and scrutinized judiciously for risks and benefits within the current workflow. Consider which committee may have oversight of this process (e.g., medication safety committee). Include this review as part of the pharmacy checklist during the approval process when new drugs are being added to the hospital formulary.

Ensure warnings are actionable. Instead of a simple "high-alert" warning, direct the end user to what action should be taken. Avoid use of negative statements or warnings. For example, "FOR TOPICAL USE ONLY" is recommended instead of "NOT FOR PARENTERAL USE."

Complete a look-alike review. If an auxiliary label is deemed necessary, compare it with other labels in use and mitigate look-alike issues (e.g., similar color, wording, size, shape, word placement).

Assess storage. Store auxiliary labels in a standard configuration in all pharmacy locations. Consider using one of the auxiliary labels to mark its storage location, and ensure consistency when the supply of labels is refilled. Consider including label storage as part of the pharmacy's monthly inspection to ensure auxiliary labels are kept organized to avoid label selection errors.

Interactive placement. When adding to a product, consider optimal placement and ensure the auxiliary label does not cover other information on the medication label. While the ISMP Targeted Medication Safety Best Practices for Hospitals recommends layering several high-leverage strategies to prevent medication errors, placing auxiliary labels on neuromuscular blocking agents that state, "WARNING: PARALYZING AGENT–CAUSES RESPIRATORY ARREST," may arguably be the most critical auxiliary label that should be utilized. In this situation, placing this auxiliary label over the vial or syringe cap of the neuromuscular blocking agent forces the end user to interact with the label. Additional applications of interactive placement of auxiliary labels should be explored.

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SAFETY brief

UPDATE: Avoid Referring to Drug Concentrations as Standard or Double Strength. In our March 13, 2025 article, Esmolol Labeled as "DOUBLE STRENGTH" May Lead to Confusion, we shared that a pharmacist reported concerns with the labeling of esmolol 2,000 mg/100 mL premixed bags which refer to the product as double strength. While we recognize that this terminology originates from the brand name reference listed drug, the concern is that there is no approved standard concentration upon which "double strength" of esmolol injection should be based. This may not match what is considered "double concentration" at all institutions. There may be a risk of errors if practitioners refer to a concentration as standard or double strength without communicating the actual concentration.

We reiterated to the US Food and Drug Administration (FDA) the risk of medication cartons and infusion labels stating double strength or double concentration, including esmolol products made by Amneal, Baxter, Eugia, Sagent, WG Critical Care, and possibly others. At that time, FDA's Division of Medication Error Prevention and Analysis (DMEPA) communicated to ISMP that "double strength" is not currently recommended for labeling, and that this position, while not yet published as formal guidance, is consistent with FDA's broader labeling safety principles. We encourage manufacturers of affected products to engage FDA about the process for updating an abbreviated new drug application (ANDA) labeling to align with current FDA labeling recommendations, as contemplated by 21 C.F.R. § 314.94(a)(8)(iv) and FDA's January 2024 guidance on ANDA labeling revisions, Revising ANDA Labeling Following Revision of the RLD Labeling Guidance for Industry.

Until this underlying labeling question is resolved at the regulatory level, organizations should take steps to ensure these products are used safely. Avoid using terminology such as "standard strength," "double strength," or any other multiple as a descriptor in all systems (e.g., electronic health record, automated dispensing cabinet, infusion pump), on pharmacy-prepared infusion labels, and when communicating concentrations.

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Optimize technology. Maximize the use of automation (e.g., EHR-generated label, intravenous workflow management system [IVWMS]) to include critical warnings. For every auxiliary label that must be manually added to the drug product, there is an opportunity for human error. Ensure critical information is prominently and consistently displayed on medication labels to minimize the need to add duplicate warnings via an auxiliary label. Ensure appropriate warnings are clearly visible for nurses in applicable technologies (e.g., MAR, automated dispensing cabinets). Evaluate whether additional clinical decision support or interactive alerts upon barcode scanning are needed. Whenever possible, maximize the use of high-leverage risk-reduction strategies such as ENFit and NRFit connectors.

Educate practitioners. During initial and annual competency assessments, educate practitioners not to rely on color alone. This practice should extend beyond auxiliary labels. Instead, read the medication label, refer to the MAR, use barcode scanning prior to administration, and follow organizational policies and procedures.

Gather feedback. Routinely meet with end users to foster communication and feedback on the auxiliary label process. Specifically ask about opportunities in which auxiliary labels could be removed or in which warnings need to be clearer to maximize effectiveness.

Report and learn from errors. Encourage practitioners to report close calls and errors that reach the patient that are related to auxiliary labels. Quarantine examples of errors (or take photos) for a deeper understanding of potential risks associated with the use of the auxiliary label. Evaluate if changes are needed and share lessons learned with staff. Report errors to ISMP.

References

1) Wogalter, MS, ed. *Handbook of Warnings*. CRC Press; 2006.
2) Cohen, MR, ed. *Medication Errors*. 2nd ed. American Pharmacists Association; 2007.
3) Institute for Safe Medication Practices (ISMP). Affirmative warnings (do this) may be better understood than negative warnings (do not do that). *ISMP Medication Safety Alert! Acute Care*. 2010;15(16):1-3.

We thank Kecia Missos, PharmD, MSPH, from UKHC, for sharing how their organization optimized medication auxiliary label oversight as well as helping to write this article.

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When possible, provide commercially available, premixed medication infusions in a standard concentration. If compounding is needed, provide standard drug concentrations and refer to the American Society of Health-System Pharmacists (ASHP) Standardize 4 Safety initiative. Report close calls and errors that reach patients to your organization's error reporting program and ISMP.

Special Announcements

Free CE and Frontline Conversations from ASHP

The American Society of Health-System Pharmacists (ASHP) is offering two **FREE** on-demand activities, Making USP <797> as Easy as 123: Overcoming Sterile Compounding Insourcing Challenges and Adult Versus Pediatric Considerations, and Level Up Your BUD Game: An Interactive, Choose Your Own Adventure Activity on Beyond Use Dates in Sterile Compounding. Continuing education (CE) credit is available for pharmacists and technicians for both activities.

Additionally, ASHP is offering two **FREE** webinars where you get to ask expert faculty questions related to USP Chapter <797>. The first Frontline Conversations session, Frontline Conversations: USP <797> in Practice—Resources, Risk, and Readiness, will be held on **June 23, 2026, from 1:00 pm to 2:00 pm EDT.** The conversation will focus on strategies for bringing back or increasing sterile compounding in healthcare facilities. No formal presentation is planned. Bring your questions for expert faculty to answer! For more information and to register, click here. Keep your eyes out for another Frontline Conversations session coming soon.

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