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ISMP Institute for Safe Medication Practices
An ECRI Company

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Still room for improvement when responding to errors noted by patients

Problem: ISMP frequently receives reports of medication errors directly from patients or their family members. Often these reports describe errors that occurred in medical offices or community pharmacies. While they are understandably troubled about the errors, the patients who report to us are also concerned about the poor responses they receive from medical office and pharmacy staff in response to the error.

Recently, a patient discovered an error during patient counseling. The patient had been taking lisinopril 30 mg, 1 tablet by mouth daily. Due to insurance coverage, the prescription was typically filled for a 30-day supply. However, the patient's prescription drug coverage changed and they requested the prescriber write a prescription for a 90-day supply. When the prescriber wrote the new prescription, they inadvertently changed the directions to take three 30 mg tablets daily, which would result in the patient taking 90 mg of lisinopril daily instead of 30 mg, which would have exceeded the maximum daily dose. The prescription did correctly indicate that the pharmacy should dispense a 90-day supply.

Despite the significant increase in the prescribed dose, the new prescription was filled. Because of the change in dose, the prescription was marked for mandatory patient counseling. During counseling, the patient confirmed that the prescription had not changed, and it was just meant to be a 90-day supply. However, rather than clarify and change the order with the prescriber, the pharmacist sold the incorrect prescription to the patient and informed them to follow up with their doctor for clarification. The patient received 270 tablets, rather than 90 tablets, along with the incorrect instructions on the bottle.

The patient followed up with the provider to inform them of the incorrect prescription. The provider then sent a prescription for lisinopril 10 mg, take 1 tablet by mouth daily. This prescription was filled by the pharmacy but not picked up due to this also being an error. The patient contacted the prescriber again. The prescriber confirmed she had made a human error when entering the dose as 10 mg instead of 30 mg. She confirmed she would correct the medication list on file. Then, she entered the medication as lisinopril 10 mg, take 3 tablets by mouth daily for 30 days instead of lisinopril 30 mg, take 1 tablet by mouth daily for 90 days.

When a different pharmacist was verifying the latest prescription, they stopped the line, called the patient, and confirmed that he was not taking 90 mg daily. He also indicated that he would be following up to review what happened with the previous incorrect prescriptions. No further information was shared with the patient from the pharmacy.

Upon follow up with the prescriber, she shared that she was thankful for the patient's attention to detail and for being aware of the risks that may arise with a prescription error. She stated that she has to keep a "close eye" on other patients who she knows are unable to do this for themselves. Unfortunately, this was viewed as inevitable rather than an opportunity to learn and improve systems.

Safe Practice Recommendations: Work with vendors and internal system analysts/developers to ensure your electronic health record (EHR) or pharmacy dispensing system provide clinical decision support with dos range checking and warnings. Systems should be able to identify doses that exceed established maximum doses and present an interactive alert to the prescriber and/or

continued on page 2 — Responding to errors >

SAFETY briefs

Look-alike QUEtiapine and ARIPiprazole bottles. A pharmacist reported the potential for wrong-drug errors involving **QUE**tiapine 50 mg tablets and **ARIP**iprazole 5 mg tablets, both marketed by Ascend Laboratories. The bottles for both products look almost identical (**Figure 1**). They are the same size, feature the strength in white lettering with a blue background, and display the same manufacturer trade dress. The small font size used for the drug names may also contribute to mistakes. While both drugs are second-generation (atypical) antipsychotic agents, their dosing regimens are different. A mix-up of these drugs could result in supra- or subtherapeutic dosing and patient harm.

Figure 1. Bottles of **QUE**tiapine (left) and **ARIP**iprazole (right) from Ascend Laboratories appear nearly identical.

One strategy to prevent mix-ups is to purchase products from different manufacturers to reduce the risk of look-alike containers. Thankfully, since the names start with either "a" or "q," it is less likely they will be stored next to one another alphabetically on a pharmacy shelf; however, they could be misplaced when stocking or returning the drugs to pharmacy shelves. Barcode scanning prior to dispensing is essential to prevent errors from reaching patients. The US Food and Drug Administration (FDA) should work with the manufacturer to reduce similarity among look-alike containers.

continued on page 2 — SAFETY briefs >

> Responding to errors — continued from page 1

pharmacist that requires acknowledgement. Pharmacies should test their dispensing systems to ensure that they will intercept doses that exceed established maximum doses.

Since 2009, ISMP has repeatedly called on organizations and practitioners to approach all patients, family members, and caregivers reporting actual or potential medication errors with transparency and empathy. And, ECRI's ***Top 10 Patient Safety Concerns 2025*** identified dismissing patient, family, and caregiver concerns as the top patient safety concern on this year's list.

It is imperative that organizations plan ahead and prepare staff to respond to errors. This includes preparing staff to stop the line at the point-of-sale and investigate the patient's concern if they say their prescription is incorrect. Policies on disclosure and apology to patients and caregivers are also a must. Review and discuss these policies and procedures with the pharmacy team so that the process is clearly understood. Regularly review the procedures for appropriateness. The policies and procedures should contain specific guidance on what to say and do, who should be contacted, particularly when all the facts of the case may not be immediately known, and who will follow up. Define when others (e.g., prescriber) should be notified of an error. Practice and role-play possible scenarios with all staff.

It is also critical that medical offices pharmacies learn from errors and engage employees in helping to implement high-leverage risk-reduction strategies. To maximize these efforts, establish a continuous quality improvement (CQI) program to detect, document, and assess errors as a means to determine the causes, develop an appropriate response, and implement strategies to prevent future errors. Share and discuss events, prevention strategies, and procedural changes with staff.

For additional recommendations, see our article *Excuse me, I think there is an error with my prescription: Practitioners should respond with empathy and honesty,* published in the February 2021 issue of this newsletter, as well as the ***Top 10 Patient Safety Concerns 2025***.

Not all blister cards are child resistant

A patient reported that their toddler was able to remove ondansetron 4 mg orally disintegrating tablets (ODT) from the manufacturer's blister card packaging and ingested more than a dozen tablets while unsupervised. Fortunately, no harm resulted from the ingestion. The pharmacy had dispensed the unit-dose blisters in a plastic resealable bag.

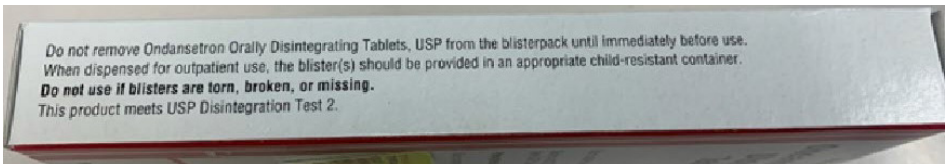

Figure 1. Information on the side panel of the ondansetron 4 mg orally disintegrating tablet carton, by Glenmark, states that the blister(s) should be dispensed in a child-resistant container.

Upon investigation, the pharmacy discovered that the ondansetron blisters, manufactured by Glenmark (national drug code [NDC] 68462-0157-13), included a warning statement on a side panel, "When dispensed for outpatient use, the blister(s) should be provided in an appropriate child-resistant container" (**Figure 1**). Unfortunately, the placement of the warning makes it easy to miss. Also, the dispensing pharmacist was unaware that certain unit-dose tablets blisters lack child-resistant features. When this medication was previously dispensed, it was placed in a vial with a child-resistant cap.

Pharmacy leadership also identified that this product was dispensed in various ways across their multiple pharmacy sites. Some locations provided the unit-dose blisters in a pharmacy vial with a child-resistant cap, while others dispensed these products in the original carton or a plastic bag. They also noted that the use of child-resistant blister packaging varied among manufacturers. Glenmark

continued on page 3 — Blister cards >

>SAFETY briefs cont'd from page 1

HIGH-ALERT

Potential risks with compounded topical finasteride products. The US Food and Drug Administration (FDA) has alerted practitioners and consumers to potential adverse events involving compounded topical finasteride that include finasteride alone or in combination with other medications such as minoxidil. These compounded products are marketed to treat hair loss.

While these products are used topically, finasteride is absorbed through the skin. Between 2019 and 2024, the FDA Adverse Event Reporting System received 32 cases of patient harm from topical finasteride product use that are consistent with events when patients have used FDA-approved oral finasteride. The reported adverse effects included erectile dysfunction, anxiety, suicidal ideation, brain fog, depression, fatigue, insomnia, decreased libido, and testicular pain. Most of the reports indicated that the adverse events continued to persist after discontinuation. Topical finasteride may also cause skin irritation, erythema, dryness/scaling, and stinging and burning.

There is also a significant risk of inadvertent exposure to others, particularly females, through accidental transfer of the applied medication via skin contact. Finasteride is contraindicated in pregnancy due to its potential to cause abnormalities in a male fetus. Women should not handle crushed or broken finasteride tablets because of the risk of absorption and subsequent potential harm during pregnancy. While the coating on intact FDA-approved finasteride tablets prevents

IMPORTANT! Read and utilize the Community/Ambulatory Care Action Agenda

Items from the **January – April 2025** issues of the ***ISMP Medication Safety Alert! Community/Ambulatory Care*** newsletters have been selected and prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors. The **Action Agenda** is available as an Excel file here.

> Blister cards — continued from page 2

does not use child-resistant blister packaging, while Rising Pharma Holdings (NDC 57237-077-10) does. Additionally, other locations only stocked 30-count bottles with child-resistant closures.

As a result of this incident, the organization is standardizing across its locations to only stock the medication in child-resistant packaging, either child-resistant bottles or unit-dose packaging. They are also standardizing the way they dispense the unit-dose blisters. Pharmacies will dispense the blisters in pharmacy bottles with child-resistant closures. Be sure to alert pharmacy staff to this situation and encourage the purchase of products in child-resistant manufacturer packaging when possible. If you are unable to do this, establish standard procedures to dispense the blisters in containers with child-resistant closures and periodically observe the pharmacy workflow to ensure adherence to these procedures. Always remind patients to safely and securely store their medications up and away, out of sight of children and pets. Refer parents to the US Centers for Disease Control and Prevention's (CDC) PROTECT Initiative to learn more about how to keep children safe by storing medications properly. If a child takes unauthorized medications, advise parents to contact Poison Control online or by phone at 1-800-222-1222.

Organizations must consider PN compatibility and stability data when applying USP <797>

Parenteral nutrition (PN) is a complex life-sustaining therapy for patients who cannot intake adequate oral or enteral nutrition. PN can contain multiple ingredients. PN can be compounded or delivered using a commercially available multi-chamber bag. PN can also be administered with an intravenous lipid emulsion (ILE) added to the PN bag (total nutrient admixture) or have the lipid injectable emulsion co-infuse with the PN (dextrose-amino acid admixture with Y-sited ILE).

The most recent revision of USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations* became official on November 1, 2023.[1] The standard reduces the risk of contamination and patient infections from compounded sterile preparations (CSPs). Categories of risk are now assigned as category 1, 2, or 3, and the interpretation of the standards has led PN to be viewed as a category 2 CSP.[1] Now, beyond-use dates (BUDs) (i.e., from the time of compounding to administration) for category 2 CSPs are 4 days at room temperature and 10 days if refrigerated.[1]

The American Society for Parenteral and Enteral Nutrition (ASPEN) has received feedback from practitioners who reported confusion with interpreting the standards, inquiring if PN should now have an extended expiration date (i.e., 4 days or 10 days). However, the BUD assigned by USP <797> is based on sterility. USP <797> states a shorter BUD must be assigned when the physical and chemical stability of the CSP is less than the BUD limit. Therefore, practitioners must also consider *compatibility* and *stability* data that is specific to each PN's components (amino acid solution, ILE, dextrose, and micronutrients) when determining the PN expiration date (i.e., the date/time the PN should no longer be administered).

Based on the literature on PN compatibility and stability,[2] ASPEN recommends PN generally has an expiration date of 30 hours at room temperature and 9 days refrigerated,[3,4] unless there is specific extended stability data for the components used in the PN formulation. Additionally, the hang time for PN should not exceed 24 hours, and the hang time for a separate ILE infusion should not exceed 12 hours.[5] The ASPEN PN Committee recently authored an article about this important topic.[6] Ensure your organization's policy and procedures related to PN follow these updated standards and include an appropriate BUD (sterility), expiration date (stability), and hang time for PN to avoid patient harm.

References

1) USP-NF (USP 43-NF 38). USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations. Rockville, MD: USP; November 1, 2023.

continued in the right column — PN >

>SAFETY briefs cont'd from page 2

contact with finasteride during routine handling, compounded topical finasteride products do not have this coating, and other compounded formulations may also lack this protective layer.

Healthcare practitioners are encouraged to educate patients on the potential risks of using compounded topical finasteride. Providers and pharmacists should alert patients about the risk of accidental transfer of medication through skin contact and the associated risks for women who are or may become pregnant. Consumers should consult with their healthcare practitioners and compounders regarding potential risks before starting treatment with compounded topical finasteride.

> PN — continued from the left

2) Boullata JI, Mirtallo JM, Sacks GS, et al. Parenteral nutrition compatibility and stability: a comprehensive review. *JPEN J Parenter Enteral Nutr*. 2022;46(2):273-99.

3) Boullata JI, Gilbert K, Sacks G, et al. A.S.P.E.N. clinical guidelines: parenteral nutrition ordering, order review, compounding, labeling, and dispensing. *JPEN J Parenter Enteral Nutr*. 2014;38(3):334-77.

4) Mays A, Ayers P, Monczka J, Cober MP. Safety in parenteral nutrition compounding. *Nutr Clin Pract*. 2023;38(6):1253-62.

5) Nickel B, Gorski L, Kleidon T, et al. Infusion therapy standards of practice, 9th edition. *J Infus Nurs*. 2024;47(1S Suppl 1):S1-S285.

6) Cogle SV, Mulherin DW, Sacks GS, Mirtallo JM. Beyond-use dates for parenteral nutrition must take compatibility and stability into consideration. *Pharmacy Practice News*. Published June 23, 2023. Accessed March 1, 2025.

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