August 2025 | Volume 24 ▪ Issue 8

ISMP Institute for Safe Medication Practices
An ECRI Company

Community/Ambulatory Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Humatrope pen distribution practices contribute to errors

Problem: A health system outpatient pharmacy reported a medication error involving **HUMATROPE** (somatropin), a growth hormone. A patient was prescribed Humatrope and received the medication cartridge. However, upon returning home and preparing to administer the dose, the patient realized they did not have the necessary device to inject the medication. The patient contacted the pharmacy, at which point it became apparent that the Humatrope pen device—required for administration—had not been provided. The Humatrope pen injection device is available directly from the manufacturer, Lilly.

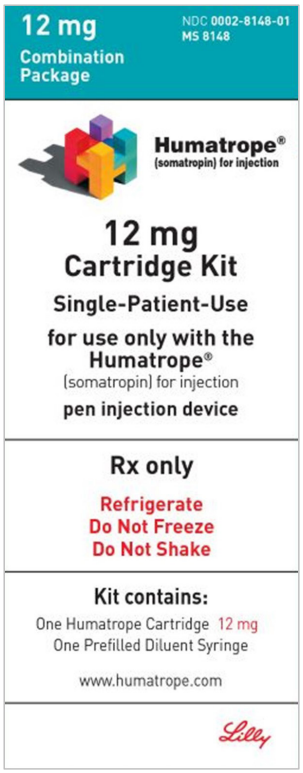

Figure 1. The principal display panel of the Humatrope 12 mg cartridge kit indicates that it is a combination product containing one Humatrope cartridge and one prefilled diluent syringe. While the label specifies that the medication is intended for use only with the Humatrope pen injection device, it does not clearly state that the pen device must be obtained separately.

Following this incident, the organization reviewed records to identify other patients who may have received only the Humatrope cartridge without the corresponding pen. One such case involved a patient who had been switched from **NORDITROPIN** (somatropin) to Humatrope due to a supply issue. Upon follow-up, the organization discovered that instead of using the required Humatrope pen administration device, the patient had been using an insulin syringe to administer Humatrope, despite the prescribing information clearly stating, "Do not transfer the contents of the Humatrope Cartridge to a syringe."

In the November 2023 issue of this newsletter, we notified practitioners that Humatrope pens are available from the manufacturer and that cartridges must be used exclusively with the matching Humatrope pen (e.g., a 12 mg cartridge must be used with a 12 mg pen). In a previously reported case, a patient was switched from 6 mg to 12 mg cartridges, but the family was not provided with the 12 mg pen. As a result, the child's parent used the 6 mg pen with the 12 mg cartridge, inadvertently administering the child a higher dose than what had been prescribed.

The organization that most recently reported this issue noted that Humatrope cartridge kit cartons do not clearly indicate that the pen device is provided separately (**Figure 1**). This can lead to confusion among both patients and healthcare providers, who may assume that the injection device is included within the carton or the included prefilled diluent syringe and cartridge constitute a complete administration system.

Typically, pharmacies only dispense the Humatrope cartridges—not the pen devices. Patients must obtain the appropriate pen separately (e.g., from the manufacturer). This distribution model increases the risk that patients may not receive the correct pen, or any pen at all. Furthermore, pharmacies may not be aware of which pen device (e.g., 6 mg or 12 mg) the patient possesses when dispensing the cartridge. Although the prescribing information specifies that the pen and cartridge strengths must match to ensure accurate dosing, this critical detail can be easily overlooked.

continued on page 2 — Humatrope >

SAFETY briefs

Patients may confuse cycloSPORINE (modified) as SandIMMUNE. Cartons and containers of cyclo**SPORINE** (modified) capsules contain a warning message alerting practitioners that the product is not bioequivalent or interchangeable with **SANDIMMUNE** (cyclo**SPORINE**) (**Figure 1**). This warning is present as mix-ups between modified and non-modified formulations of cyclo**SPORINE** have occurred, resulting in therapeutic failures. Sand**IMMUNE**, a non-modified form of cyclo**SPORINE**, has decreased bioavailability compared to modified formulations (e.g., **NEORAL**, **GENGRAF**).

Figure 1. The primary display panel of a carton of cyclo**SPORINE** (modified) 100 mg capsules displays a warning that it is not bioequivalent or interchangeable with Sand**IMMUNE** (cyclo**SPORINE**).

However, this warning message confused a patient recently. Upon admission to the hospital, the patient mistakenly told the provider, nurse, and medication history technician that they were taking Sand**IMMUNE** 100 mg capsules twice daily instead of cyclo**SPORINE** (modified) 100 mg capsules twice daily. They had read this drug name in the warning message on their carton of cyclo**SPORINE** (modified). As a result, the non-modified formulation of cyclo**SPORINE** was ordered and administered to the patient twice before a pharmacist intercepted the error.

Alert staff of this situation. Reinforce the need to independently verify which formulation of cyclo**SPORINE** a patient is taking. Flag prescriptions for cyclo**SPORINE** for

continued on page 2 — SAFETY briefs >

> Humatrope — continued from page 1

Safe Practice Recommendations: Ensure treatment protocols and counseling guidelines for Humatrope (and other similarly packaged somatropin products) include prompts to verify with the patient/parent/caregiver that they have the correct pen device and that it matches the prescribed cartridge strength. If the patient lacks a pen or has a mismatched device, coordinate with the provider and manufacturer to obtain the correct pen. Reinforce during patient counseling the need to verify that the cartridge strength and the strength indicated on the pen device match. Ideally, the company should design cartridges and pens such that each cartridge strength can only connect to the matching pen device.

Wrong drug error involving return-to-stock vial

Problem: A pharmacy reported an incident in which a patient inadvertently received a mixture of two controlled substances. The prescription was for **HYDRO**codone-acetaminophen, but during the filling process, a pharmacy technician mistakenly retrieved both a manufacturer's bottle of **HYDRO**codone-acetaminophen and a return-to-stock (RTS) bottle of oxy**CODONE**-acetaminophen. The technician poured the contents of the RTS bottle and the manufacturer's bottle onto an Eyecon counting machine. The Eyecon uses a camera to visually count and identify incorrect solid oral dosage forms. However, according to the reporter, the tablets of both drugs look nearly identical with very similar shapes, and thus the counting machine did not recognize that there were two different medications on the counting tray.

The technician completed the dispensing process and passed the prescription to the pharmacist for verification. Unfortunately, the pharmacist also did not recognize that the vial contained a mix of two different medications. The prescription was dispensed, and the patient began taking the medication.

The following day, the patient noticed the presence of different tablets in the vial and contacted the pharmacy. The pharmacy promptly corrected the error, provided the correct quantity of **HYDRO**codone-acetaminophen, and segregated the oxy**CODONE**-acetaminophen tablets for return with expired medications.

The pharmacy reported a number of factors that contributed to this event. Their pharmacy dispensing system does not print an RTS label with a usable barcode. Instead, staff manually cover the patient's name with a privacy label when returning a prescription vial to stock. Only the correct manufacturer's bottle of **HYDRO**codone-acetaminophen tablets was scanned during the Eyecon process; the RTS vial was not. Breakdowns occurred in the manual verification process of the National Drug Code (NDC) of the RTS medication during both dispensing and verification; the pharmacy technician and pharmacist did not notice the RTS bottle contained a different medication (and NDC). Also, it is thought that the RTS vial of oxy**CODONE**-acetaminophen was possibly stored on the wrong shelf with bottles of **HYDRO**codone-acetaminophen. Finally, the visual similarity between the two medications made it difficult to detect the error during counting and verification.

Safe Practice Recommendations: Due to the ongoing reports of RTS-related errors and the potential for patient harm, we published *Best Practice* 7, Maximize the use of technology to prevent errors during the return-to-stock (RTS) process, in the ISMP ***Targeted Medication Safety Best Practices for Community Pharmacy***. It is important for both pharmacy dispensing system vendors as well as pharmacies to implement the different elements of this *Best Practice*. For example, pharmacy dispensing systems should generate specific labels to apply to prescription bottles that require RTS. The RTS labels should include the drug name, dosage strength, expiration date, description (e.g., tablet shape, color, imprint code), and a barcode that can be used when filling a subsequent prescription. Utilize barcode verification throughout the RTS process to ensure the correct RTS label is placed on the correct RTS prescription and during subsequent prescription fills. After affixing an RTS label to the prescription vial, place the RTS medications on pharmacy

continued on page 3 — Return to stock >

>SAFETY briefs cont'd from page 1

mandatory counseling. Leverage technology to prompt mandatory patient education for these products. Be sure to include a review of the medication name and formulation of the product dispensed. Review the warnings on cartons and/or containers of cyclo**SPORINE** (modified) capsules with patients. Teach patients that Sand**IMMUNE** is not the name of the cyclo**SPORINE** (modified) product and that using this name on medication history documents may contribute to errors.

Baby food or drug disposal pouch? A pharmacist recently brought to our attention a potential safety concern involving the drug disposal product *Rx Destroyer*. While this product is available in various sizes and containers, it comes in pouches that resemble those used for baby food or squeezable snack containers (**Figure 1**). Although the risk of selection errors in a retail setting may be low, once the pouch is brought into the home, there is a possibility that a child could mistake it for a food item and attempt to ingest it. Fortunately, the Rx Destroyer pouch has a child-resistant cap. However, this feature may not prevent all accidental ingestions by curious children.

Figure 1. The Rx Destroyer pouch (left) looks similar to available baby food pouches (right).

This example underscores the importance of conducting a failure mode and effects analysis (FMEA) before introducing new products or packaging to the market. Such proactive assessments can help identify potential safety risks and guide necessary design changes. In addition, pharmacy staff and others who distribute these pouches should educate patients on safe storage practices. Specifically, these pouches should be kept up, away, and out of sight of

continued on page 3 — SAFETY briefs >

> Return to stock — continued from page 2

shelves and, as appropriate, use these to fill subsequent prescriptions. Develop functionality to automate and guide the use of available RTS medications to fill prescriptions before reverting to sending prescriptions to an automated dispensing system for filling.

The reporting pharmacy also identified opportunities to enhance their controlled substances perpetual inventory process. At the time of the event, dispensed quantities were documented electronically only after dispensing. The pharmacy is now exploring ways to incorporate a pre-dispensing inventory check, especially for medications with RTS vials, to improve accuracy and accountability.

Worth repeating...

Another mix-up between Biktarvy dosage strengths

An adult patient with human immunodeficiency virus (HIV) was prescribed the wrong strength of **BIKTARVY** (bictegravir/emtricitabine/tenofovir alafenamide). Instead of prescribing Biktarvy 50-200-25 mg tablets, the physician ordered Biktarvy 30-120-15 mg, which is the appropriate strength for pediatric patients weighing 14 to less than 25 kg. The error was not intercepted by the outpatient pharmacy and they dispensed a 90-day supply of the lower strength product to the patient. About a month later, when the patient was seen again at the clinic, the outpatient medication reconciliation technician discovered the error, noticing that the two dosage strengths for Biktarvy were listed on the patient's home medication list. The infectious disease provider was notified, but it was too soon to know the extent of any potential patient harm after taking the suboptimal therapy for almost a month.

In the December 2022 and August 2023 issues of this newsletter, we wrote about dosing errors involving Biktarvy. In one case, a patient who had been stable on the correct adult dose of Biktarvy was prescribed and dispensed the pediatric formulation for multiple months following a hospitalization. By the time the error was discovered, the patient's viral load was detectable, which was attributed to the prolonged underdosing.

To help prevent errors, some key points are ***Worth* repeating.** Educate prescribers, nurses, and pharmacy staff who may manage HIV medications on the various dosing regimens and combination therapies. Create weight-based order sentences with dose range checking in the electronic health record (EHR) to guide prescribers to select the correct dose. Pharmacy dispensing systems should alert and prevent entry of the pediatric formulation for adult patients using patient information such as age and/or weight. If your organization only services adult patients, consider removing the pediatric dose from your preferred drug list.

Also, this report highlights the need and benefit of robust medication reconciliation processes in both medical offices and outpatient pharmacy settings. Inconsistent knowledge and documentation of medications is a known cause of medication errors, which can negatively affect patient outcomes. Discrepancies in medication histories and incomplete or inaccurate medication history collection and reconciliation are common causes of errors, especially during transitions in care. Establish expectations for conducting medication history collection, verification, and reconciliation. Consider designating the specific and appropriate individuals who should complete each process step to drive improving safe care handoffs for patients.

>*SAFETY* briefs cont'd from page 2

children. Once used and the container is full, Rx Destroyer pouches should be disposed of safely in the household trash.

Special *Announcements*

Just Culture Scholarship

Applications are now being accepted for the ***Judy Smetzer Just Culture Champion Scholarships***. For more information and to submit an application, click here. The deadline to apply is **September 30, 2025**.

Virtual MSI workshop

Join us for our next ***ISMP Medication Safety Intensive (MSI)*** workshop for **community and specialty pharmacies**. The two-day virtual workshop is designed to help you successfully address medication safety challenges that impact patient safety. The virtual program will be held **September 26** and **October 3, 2025**. For more information and to register, please click here.

Share Your Stories with Us

Articles in this publication are based on actual reports from practitioners. We'd like to hear from you too! Please share reports of medication errors and prevention recommendations, in confidence, with colleagues in the United States and worldwide. Errors may be reported online or by calling 1-800-FAIL-SAF(E). ISMP communicates product-related issues with the US Food and Drug Administration and companies whose products are mentioned in reports. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

To subscribe: www.ismp.org/ext/1369

ISMP Medication *Safety Alert!* Community/Ambulatory Care (ISSN 1550-6290)

Report medication and vaccine errors to ISMP: Please visit www.ismp.org/report-medication-error or call 1-800-FAIL-SAF(E), ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

Editors: Michael J. Gaunt, PharmD; Shannon Bertagnoli, PharmD; Ann Shastay, MSN, RN, AOCN; Rita K. Jew, PharmD, MBA, BCPPS, FASHP. ISMP, 3959 Welsh Road, #364, Willow Grove, PA 19090. Email: ismpinfo@ismp.org; Tel: 215-947-7797.