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ISMP
An ECRI Affiliate

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

Advise patients to beware of desiccants in Cresemba unit-dose blisters

Problem: Astellas Pharma manufactures **CRESEMBA** (isavuconazonium sulfate) in blister packs containing 74.5 mg or 186 mg capsules. It is an antifungal agent indicated for the treatment of invasive aspergillosis and mucormycosis in adults and pediatric patients 6 years of age and older who weigh at least 16 kg. The 74.5 mg strength is packaged in a carton of 7 blister packs. Each blister pack contains five capsules per sheet; each capsule is packaged with a corresponding desiccant. The 186 mg strength is packaged in a carton of 2 blister packs. Each sheet contains seven capsules, and again, each capsule is packaged with a corresponding desiccant (**Figure 1**).

Each desiccant blister is labeled with "Contains desiccant to protect from moisture. Do not open. Do not eat." However, this warning may be missed as it is only printed on one side of the blister and is in a small font size. The warning "DO NOT EAT" is also included on the desiccant itself but it may also be difficult to read and be missed. Because a desiccant-containing blister could be easily mistaken for a medication-containing blister (**Figure 2**), there is a risk that a patient may accidentally ingest a desiccant.

That is exactly what happened in one case reported to ISMP. A nurse accidentally handed both the capsule and the desiccant to a patient. The patient then ingested both. The patient later reported throat discomfort, describing it as being scratched by the desiccant.

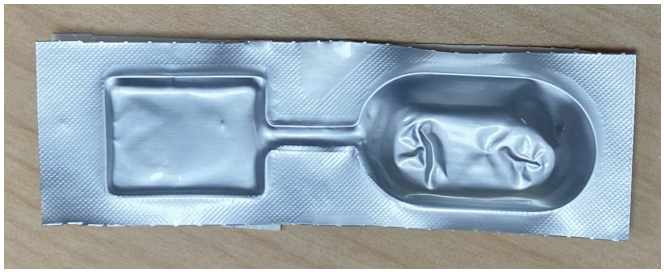

Figure 1. Individual blister containing one desiccant (rectangular well on left) and one Cresemba 186 mg capsule (oval well on left).

We have previously reported on patients who have accidentally ingested desiccant capsules from medication bottles and blister packs. For example, multiple patients ingested the desiccant tablets included in the everolimus packs manufactured by Biocon Pharma.

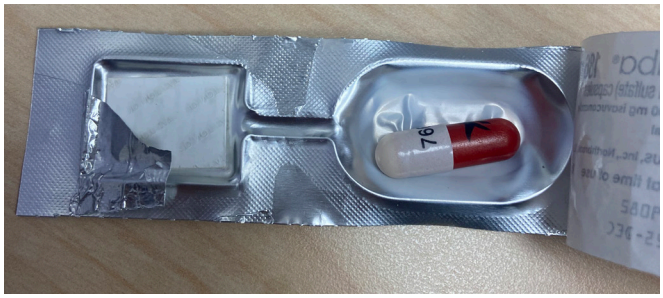

Figure 2. Both the desiccant (left) and Cresemba capsule (right) may be accessed and ingested if the backing is completely removed from the blister.

Safe Practice Recommendations: Alert pharmacy staff to this packaging issue as they may never open the carton to see the individual blisters. In the pharmacy computer system and on the cartons, mark these products for mandatory patient education. It is critical that patients know that these blister packs contain desiccants that should not be swallowed or eaten. In fact, it is good practice to warn patients about desiccants whenever manufacturer containers are dispensed.

SAFETY briefs

Hiberix diluent syringe administered as vaccine. **HIBERIX** (*Haemophilus b* conjugate vaccine) is recommended to prevent invasive disease caused by *Haemophilus influenzae type b* (Hib) in pediatric patients. It may also be considered for adults who have not received the childhood Hib series and are at increased risk for invasive Hib disease due to sickle cell disease, anatomic/functional asplenia, or splenectomy. The vaccine was previously only available in cartons containing ten single-dose vials of lyophilized antigen component and ten single-dose vials of sterile saline diluent. Before administration, 0.6 mL of diluent must be used to reconstitute the lyophilized antigen. More recently, GSK, the manufacturer of Hiberix, has made the vaccine available in cartons containing ten single-dose vials of lyophilized antigen and ten single-dose, prefilled syringes containing sterile saline diluent. Before administration, the volume of diluent in the prefilled syringe must be injected into the vial containing the lyophilized antigen.

A patient status-post splenectomy presented to a pharmacy for the Hiberix vaccine. The pharmacist who selected the vaccine from storage and verified the order was familiar with the two-vial vaccine formulation but not the new carton configuration containing vials of lyophilized antigen and prefilled syringes of diluent. They assumed the prefilled syringe of diluent contained vaccine.

The patient decided to come back at a later time to receive the vaccine, so the pharmacist returned the syringe to the refrigerator. It was then that they realized the prefilled syringe only contained diluent. They looked inside the carton and found three vials of lyophilized antigen "hidden" under the carton flap. However, they only found one diluent syringe in the carton. It was determined that two patients likely received only the diluent in previous vaccine administrations.

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Hazard: Unmet technology support needs for home care patients

ISMP's affiliate, ECRI, recently released the ***Top 10 Health Technology Hazards for 2025***. Now in its 18th year, ECRI's annual report identifies health technology concerns that warrant attention by patients, healthcare leaders, and industry. ECRI's team of biomedical engineers, clinicians, and healthcare management experts, along with ISMP medication safety experts, follow a rigorous process to select hazards for the annual list, drawing insight from incident investigations, reporting databases, and independent medical device testing. We wanted to draw your attention to one hazard in particular. Coming in at number two is the unmet technology support needs for home care patients.

For many patients, healthcare at home is an attractive alternative to hospital-based treatment, allowing a more comfortable and convenient care experience. But delivering care in the home setting also has unique challenges, particularly when the patient or a family member is responsible for operating a complex medical device. Devices often are not designed with the home user in mind, and patients and caregivers may lack the expertise needed for proper device operation. Severe harm can result if patients or their caregivers do not fully understand how to use and troubleshoot a device.

Traditionally, medical devices (e.g., infusion pumps, dialysis machines, ventilators) have been used under clinical supervision in acute care settings; however, their use is increasing in the home setting. Inappropriate setup and management of devices used in the home can increase the risk of patient harm. The likelihood of such harm may increase if providers or health technology management (HTM) professionals neglect key HTM practices. Such practices include assessing device usability in the context of the patient's or caregiver's abilities (e.g., when selecting a device for use), supplying the appropriate accessories for safe use of the device, and providing sufficient training or instructions for proper device function and maintenance.

ECRI has identified several factors that have contributed to reported events and patient harm related to the improper setup or lack of familiarity with medication devices used in the home setting. For example, an infusion pump was programmed incorrectly leading to hospitalization of the patient. In another case, a patient died after a venous needle became dislodged during dialysis. Additionally, patients and caregivers may not recognize misleading results or may misinterpret device readings, possibly leading to either a false sense of security or unnecessary concern. Also, home users may not know how to cope with device malfunction or problems caused by misuse, potentially causing care delays or serious patient injury or death. Supplies or accessories may be damaged because caregivers did not realize they must be stored within a specific temperature range.

Of course, there are other medication-related devices (e.g., glucometers, pen devices, on-body injectors, nebulizers, implantable insulin pumps) that many patients and/or their caregivers must manage in the home. These, while often designed for patients' own use, may still present the risk of errors for some patients. Appropriate patient selection and education are critical to enable patients to use these devices effectively and safely.

To help prevent errors, HTM professionals, healthcare facilities, medical offices, retailers, ambulatory care and home infusion pharmacies, and durable medical equipment providers should consider the following recommendations. Form a multistakeholder team to establish a process to assess patients and caregivers, before providing any medical device, to determine whether they can use the technology appropriately. When feasible, perform assessments of the home environment to identify infrastructure and user needs. Educate patients, family members, and caregivers on the appropriate use of the technology, and confirm that they understand the relative risks and benefits involved. When purchasing, recommending, or prescribing devices that will be used in patient homes, be sure to consider the appropriateness of the device for home healthcare use. Look for devices that have been designed and tested specifically for use by patients and consumers outside a clinical environment. Before deploying equipment to the home care setting, confirm that: the device is configured to

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To reduce the risk of errors, establish a process to keep the Hiberix vial and prefilled syringe together (e.g., band or bag them together). Post a note or signage where these products are stored alerting staff that one syringe and one vial will be needed. Work with computer vendors and/or internal developers to configure the system to enable (and require) scanning of both the vaccine and corresponding diluent barcodes during preparation/administration. When the medical office, clinic, or pharmacy receives a new product, conduct a review to identify potential risks with the product's design and storage. Educate all vaccinators about any new vaccines or vaccine configurations. Provide regular competency assessments for all staff who prepare and administer vaccinations.

Look-alike amiodarone and traMADol bottles. A pharmacy reported a close call when dispensing a prescription for traMADol 50 mg tablets. The manufacturer bottles containing 100 tablets look nearly identical to the 60-count bottles of amiodarone 200 mg tablets (**Figure 1**). Both products are manufactured by Unichem Pharmaceuticals and use the same label design and red color bands at the top and bottom of the labels. In addition, the red color patterns for the dosage strength background increase the look-alike similarities.

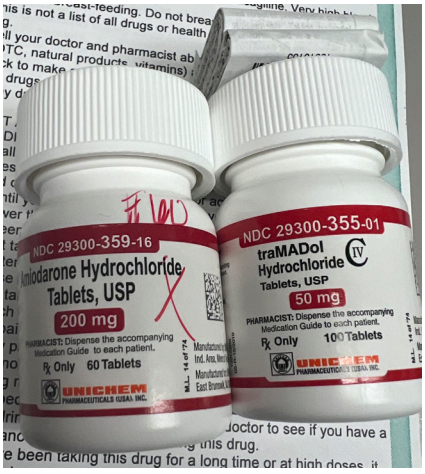

Figure 1. Look-alike bottles of amiodarone (left) and traMADol (right) from Unichem Pharmaceuticals.

In May 2023, we wrote about the look-alike nature of Unichem's bottles of allopurinol 100 mg, amLODIPine 2.5 mg, and amitriptyline 10 mg. Consider purchasing look-alike products

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minimize setup burden on the patient or the caregiver; all necessary consumables, cables, batteries, and similar items are sent along with the device, with clear instructions on where and how to acquire and store replacements; the delivery package includes use and troubleshooting instructions that are clearly understandable (e.g., using simple and concise language, avoiding medical jargon); and the contact information of the provider and/or manufacturer liaison is included. Visit Unmet Technology Support Needs for Home Care Patients for more information and risk-reduction strategies.

Alert! InFLIXimab-dyyb is the nonproprietary name for both Inflectra and Zymfentra

Problem: The US Food and Drug Administration (FDA) has approved two brand name biologics with the same nonproprietary name and 4-letter suffix, in**FLIX**imab-dyyb; however, they are not biosimilars or interchangeable with each other. **INFLECTRA** is a biosimilar of the reference product **REMICADE**. As such, it is available as a 100 mg lyophilized powder, single-dose vial for reconstitution and dilution. It is approved for adults and pediatric patients 6 years of age and older with Crohn's disease or ulcerative colitis. It is also approved for the treatment of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis in adults.

ZYMFENTRA is a reference drug and is not a biosimilar of or interchangeable with Remicade. It is available in 120 mg/mL, single-dose prefilled syringes and prefilled pens. It is approved for adults as maintenance treatment of moderately to severely active Crohn's disease or ulcerative colitis following treatment with an intravenously administered in**FLIX**imab product.

In the July 2024 article, *Many adalimumab biosimilars may look similar*, we alerted practitioners that there are branded and unbranded versions of adalimumab (e.g., **HYRIMOZ** [adalimumab-adaz] and adalimumab-adaz) that share the same nonproprietary name and 4-letter suffix. However, this is the first time we have seen two brand name products share the same nonproprietary name and 4-letter suffix (i.e., in**FLIX**imab-dyyb).

Specialty pharmacies may stock both drugs: Zymfentra, which is the subcutaneous injection that can be self-administered by the patient; and Inflectra, which is a lyophilized powder that requires preparation and intravenous administration by a provider, but may be required to be 'bagged' under the pharmacy benefit and dispensed to the patient or provider. If the lyophilized powder (Inflectra) is sent to the patient instead of the subcutaneous formulation (Zymfentra), there is a risk of misuse by the patient. Conversely, if a clinic received Zymfentra instead of Inflectra, they could potentially administer the subcutaneous injection to the patient via the incorrect route (intravenously) or administer it via the correct route but it would be the incorrect formulation.

Safe Practice Recommendations: We have notified FDA and Celltrion, the manufacturer of both products, about the potential for mix-up. However, per FDA-approval review documents, Zymfentra can have the same nonproprietary name and suffix as Inflectra because they are the same drug, only with a different strength, dosage form, and route of administration. To reduce the risk of errors, confirm with computer and drug information vendors that these are listed as separate products in electronic systems. Consider using the brand name when prescribing these medications. In electronic prescribing systems, ensure order sentences are associated with the correct product. In the pharmacy, verify that the dosage form and route of administration is appropriate for the prescribed and dispensed product. Educate staff about the product differences, noting that they are not interchangeable with each other, and about the potential to mix them up. At the point-of-sale, open the bag and have the patient check to make sure they are receiving the correct medication. If the medication is shipped to the patient, instruct them to carefully inspect the medication upon receipt, comparing the medication name and quantity to what is listed on the pharmacy label. Encourage patients to contact the pharmacy if they have any questions or concerns.

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from different manufacturers. If you currently have these products, consider storing them separately; make sure staff are aware that they have been separated and where to locate the medications. Employ barcode scanning during dispensing and verification, scanning each bottle used to fill a prescription.

Special Announcements

Virtual MSI workshop

Join us for our first ***ISMP Medication Safety Intensive (MSI)*** workshop of the year for **community and specialty pharmacies**. The two-day virtual workshop is designed to help you successfully address current medication safety challenges that impact patient safety. The virtual program will be held **April 25** and **May 2, 2025**. For more information and to register, please click here.

ASHP free webinars

The American Society of Health-System Pharmacists (ASHP) is offering two **FREE** webinars: *Achieving Your Personnel Best: Training Personnel in USP Chapter 797 and Opportunities for Quality Assessment Plans*, on **April 8, 2025**; and *IV Been There Too: Safely and Effectively Incorporating Technology and a Designated Person in USP <797> Compliance*, on **April 22, 2025**. Continuing education (CE) credit is available for pharmacists and technicians. To register, please click on the program titles.

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