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ISMP

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

Ongoing confusion with different products that use the Ellipta inhaler device

In 2013, GlaxoSmithKline (GSK) introduced **ELLIPTA**, a circular inhaler device capable of combining several active ingredients. The Ellipta brand name for this inhaler device was imbedded in the drug names of five products that use the device:

- **BREO ELLIPTA** (fluticasone and vilanterol), for asthma and chronic obstructive pulmonary disease (COPD)
- **ARNUITY ELLIPTA** (fluticasone), for asthma
- **ANORO ELLIPTA** (umeclidinium and vilanterol), for COPD
- **INCRUSE ELLIPTA** (umeclidinium), for COPD
- **TRELEGY ELLIPTA** (fluticasone, umeclidinium, and vilanterol), for COPD

Through QuarterWatch™, an ISMP surveillance program that monitors adverse event reports submitted to the US Food and Drug Administration (FDA), we recently investigated 557 reports indicating that patients and healthcare providers were confusing these inhaler products that use the same Ellipta device but have different active ingredients (www.ismp.org/ext/52). The reports had been submitted to the FDA over 12 months between October 2016 and September 2017. Compared to all other drugs examined during this period, 557 adverse event reports was a very large number. Most of the errors involved Breo Ellipta (48%) and Anoro Ellipta (43%).

Causes of confusion. While the drug brand names (e.g., Breo, Anoro) are, by design, sufficiently unique to identify the products without the inhaler device information, some practitioners and patients appear to believe the products are named Ellipta or are mixing them up because of the common Ellipta name. A *Safety Wire* in the September 2017 newsletter noted this problem after ISMP received reports of confusion between the various inhalers, particularly when practitioners refer to these products only by the device name Ellipta and not the associated drug brand name. In that *Safety Wire*, we described a dispensing error in which a prescription for Incruse Ellipta was misread, and the more familiar Breo Ellipta inhaler was dispensed. The five products also come in similar packaging, differing only in color, brand name, and ingredient specifications. Once the package is opened, the inhalers are of similar design, shape, and size.

Figure 1. Image from website for Breo Ellipta (left) compared to the actual product (right).

Online instructional videos and other materials for these products further increase the risk of confusion because they do not accurately distinguish between products. If consumers or practitioners visit the product websites to learn how to use this new inhaler device, they are exposed to erroneous and misleading images of the product. For example, at www.mybreo.com/, the image of the Breo Ellipta inhaler is different than the actual product. The web version prominently features only the "Breo" brand name, and the label contains no other information; "Ellipta" is missing, as are the generic drug

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ISMP Survey on IV Push Medication Practices

If you are a practitioner who administers **intravenous (IV) push medications to ADULTS**, please take our survey on IV push medication practices! The IV push route of administration is defined as the direct, manual administration of a medication using a syringe, usually under pressure, connected to an IV access device (this does not include the use of a syringe pump). In the past few years, some practitioners have had to change the way they administer IV push medications due to ongoing drug shortages and other conditions that impact drug availability. In other cases, variability around practices associated with IV push medications have been linked to how each practitioner has been taught this critical skill.

ISMP is attempting to understand current practices and would appreciate your participation in this important survey even if you participated in our first survey a few years ago. Please view our survey on **pages 4-5**, then go to www.ismp.org/ext/49 to submit your responses by **August 31**.

SAFETY wire

Preventing SUMAtriptan injection wrong route errors. On six occasions within a 4-month period in the same health system, **SUMA**triptan has been given intravenously (IV) instead of subcutaneously. The errors have occurred in both large and small hospitals in the health system and in medical-surgical units and the emergency department.

Although the health system uses a barcode scanning medication administration system to verify that the right product at the right time is in hand for the

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> **Ellipta**—continued from page 1

names, strengths, and other important label information. The online picture of the inhaler label does not resemble the actual Breo Ellipta label except in color (**Figure 1**, on page 1).

Worse yet, at www.ismp.org/ext/11, an instructional video about how to use the Breo Ellipta inhaler portrays the device with a label that only reads "Ellipta" (**Figure 2**). This perpetuates confusion between the products using the same Ellipta device but with different active ingredients. Or, it could make patients who watch the video believe they have been dispensed the wrong drug.

Figure 2. Image from Breo Ellipta video instructions only includes the device name on the product label.

Here's what you can do: Become familiar with the various products using the Ellipta inhaler device, and recognize that the name "Ellipta" is a device, not a drug. Educate staff about the risk of confusion, and do not refer to these products by the name "Ellipta" alone—use the full product names. Teach patients who are prescribed these products their full name, how to use the inhaler, and that they will encounter inaccurate product portrayals on product websites. Although ISMP saw few error reports for Arnuity Ellipta versus Anoro Ellipta, be aware of the potential for confusion between these products with similar brand names.

Dangerous abuse of a 40-year-old over-the-counter medication, loperamide

The emergence of a new risk with loperamide (e.g., **IMODIUM A-D**, others), a 40-year-old antidiarrheal drug long available over-the-counter (OTC), begins in the medical literature with stories about fatal and near-fatal cardiac disorders linked to intentional overdoses. One story involves a 39-year-old woman who presented to an emergency department (ED) after experiencing episodes of seizure-like activity.[1] While being evaluated in the ED she experienced two more seizures, one while connected to a cardiac monitor which exposed a life-threatening dysrhythmia. A loperamide overdose was the cause. In this case, the woman had a substance abuse disorder and had been taking 50 to 100 loperamide (2 mg) caplets a day, instead of the recommended maximum dose of 4 caplets (8 mg total).

Loperamide is an opioid that is 40-50 times more potent than morphine in the gastrointestinal tract. But absorption from the gut is poor, and little drug passes the blood-brain barrier at normal doses; thus, it takes a large amount of loperamide to induce a euphoric high or cope with withdrawal symptoms. Thus, substance abusers may take 10 to 20 times the recommended dose to achieve effects that would be similar to taking an opioid such as morphine or oxy**CODONE**. The primary medical problem with a loperamide overdose is that it can cause potentially fatal cardiac events including QT interval prolongation, torsades de pointes or other ventricular arrhythmias, and cardiac arrest.

An event in which a 19-year-old was found dead at home after hosting a party revealed another problem: standard toxicology screens detected loperamide, but not loperamide overdoses.[2] When the medical examiner reviewed 21 deaths where loperamide had been detected, mass spectrometry established that loperamide overdoses contributed to 19 of the 21 deaths.[3] Poison control centers also reported that loperamide overdoses had doubled between 2009 and 2015.[4]

In June 2016, the US Food and Drug Administration (FDA) released a Drug Safety Communication (www.ismp.org/ext/53) that loperamide abuse was causing serious and fatal cardiac events. The warning was apparently based on 48 case reports the FDA received

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> **SAFETY**wire continued from page 1

right patient, the technology cannot detect if the drug is then subsequently administered by the wrong route. Most errors have occurred while practitioners were administering several IV medications to patients, and then forgot that **SUMA**triptan should be administered subcutaneously. No other causal patterns have been identified.

To support correct subcutaneous administration, the health system is devising a kit that contains the drug vial, a 1 mL syringe, and a 27-gauge subcutaneous needle packaged in a small Ziploc bag. The bag has a label on the outside, stating the name and dose of the drug

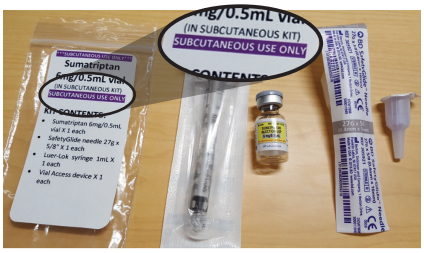

Figure 1. SUMAtriptan kit contains materials for subcutaneous injection, including a subcutaneous needle.

along with several distinct warning statements that it is intended for "Subcutaneous Use Only" (**Figure 1**).

Other risk-reduction strategies include having pharmacy prepare and dispense syringes of **SUMA**triptan as needed, with auxiliary labels to warn about subcutaneous use only. Prompting nurses to document the location of the subcutaneous injection on the medication administration record may also serve as a reminder that the drug should be administered by that route. There are also autoinjectors and pens available, which hospitals may consider using to prevent wrong route errors. These devices are set to administer the medication by the subcutaneous route.

Finally, healthcare facilities may also consider stocking the nasal formulation of **SUMA**triptan, which has a similar onset of action, in appropriate patient care areas such as the emergency department. This would allow for quicker treatment without having pharmacy prepare and dispense syringes of **SUMA**triptan.

> **Loperamide**—continued from page 2

over 39 years—a small number in the FDA reporting system which typically captures more than 75,000 serious and fatal injuries per quarter. In January 2018, FDA issued an updated Drug Safety Communication (www.ismp.org/ext/54), reporting that it was working with the manufacturers to develop abuse-resistant packaging with fewer doses.

While FDA acted promptly, published a detailed risk assessment, and followed up with additional action to reduce those risks, it took years to identify the problem of abuse. Even today, the true incidence of overdoses remains unknown. Whether this is a rare but novel form of abuse or a substantial safety issue cannot be determined.

References

1) Katz KD, Cannon RD, Cook MD, et al. Loperamide-induced torsades de pointes: a case series. *J Emerg Med.* 2017;53(3):339–44.
2) Mukarram O, Hindi Y, Catalasan G, Ward J. Loperamide-induced torsades de pointes: a case report and review of the literature. *Case Rep Med.* 2016;2016:4061980.
3) Bishop-Freeman SC, Feaster MS, Beal J, et al. Loperamide-related deaths in North Carolina. *J Anal Toxicol.* 2016;40(8):677–86.
4) Borron SW, Watts SH, Tull J, et al. Intentional misuse and abuse of loperamide: a new look at a drug with "low abuse potential." *J Emerg Med.* 2017;53(1):73–84.

Assessment data workbook available to participants

The **Preliminary Comparative Data from the ISMP Medication Safety Self Assessment® for High-Alert Medications** workbook is now available to participants who submitted their findings to ISMP. To access the workbook and associated worksheets, log in to your account at: https://ismpassessments.org/high_alert/ and click on the links titled "Results Workbook" and "Results Worksheets" in the top right corner of the page.

2018-2019 ISMP *Fellows*

ISMP welcomes three new **ISMP Medication Safety Management** Fellows.

Samantha (Sammy) Burton, PharmD, just completed a Fellowship in the Basics of Medication Safety, Quality, and Informatics at MCPHS University/Saint Vincent Hospital in Worcester, MA. She received her Doctor of Pharmacy from Purdue University (Indiana). Her Fellowship is sponsored by Baxter International Inc.

Farzana Samad, PharmD, had recently been working as a clinical staff pharmacist at Baptist Hospital of Miami in Miami, FL. She received her Doctor of Pharmacy from Nova Southeastern University, College of Pharmacy (Florida). Her Fellowship is sponsored by Express Scripts Foundation.

Alexander (Alex) Shilman, PharmD, is an active duty US Army Officer who holds the rank of Lieutenant Colonel. He most recently served as the Chief of Pharmacy at the Army Medical Department Center and School & US Army Health Readiness Center of Excellence, Fort Sam Houston, TX. He received his Doctor of Pharmacy from the University of Toledo (Ohio). His Fellowship is supported by the US Army.

Special *Announcements*

Free Baxter-sponsored webinar

Join us on **July 19** for a **free** webinar, ***Choosing Safe Practices for IV Push Medication Use in Adults: Addressing Risk in Challenging Times***. Presenters will describe the current challenges with IV push medications that threaten safety and discuss best practices and error-reduction strategies identified in *ISMP's Safe Practice Guidelines for Adult IV Push Medications*. For details and to register, visit: www.ismp.org/ext/50.

Nominate Safety Advocates for ISMP Cheers Awards

Each year, ISMP celebrates individuals, institutions, and groups that have demonstrated an exemplary commitment to medication safety and medication error prevention through innovative projects, programs, educational efforts, standard setting, and/or research. Nominations for this year's awards will be accepted through **September 7, 2018**. Medication safety advocates from all healthcare disciplines and practice areas, including community, acute, long-term, and home care settings, are encouraged to submit. Please visit www.ismp.org/cheers-awards to obtain more information, submit a nomination, or make a donation to support ISMP's medication safety efforts.

One hour FREE CE

You can obtain one hour of **FREE** nursing CE credit by reading the *ISMP Medication Safety Alert! Nurse AdviseERR* newsletter. The questions cover topics highlighted in issues from the past 6 months (January to June 2018). Once you receive a passing score, a certificate will be sent to your email address. To take the test, visit: www.ismp.org/nursingce.

ISMP INSTITUTE FOR SAFE MEDICATION PRACTICES

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

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For questions 1-6, please indicate how often you engage in the following practices associated with IV push medications for ADULTS using the following KEY: Never = 0% of the time; Rarely = 1-10% of the time; Sometimes = 11-50% of the time; Often = 51-95% of the time; Always = greater than 95% of the time

1 How often are IV push medications provided in pharmacy-prepared or commercially available ready-to-administer syringes?
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always ☐ Comments: _____

2 How often do you withdraw medication from one syringe (or syringe cartridge) into another syringe to administer some or all of an IV push medication dose?
☐ Never ☐ Rarely* ☐ Sometimes* ☐ Often* ☐ Always* ☐ Comments: _____

***If you withdraw medication from one syringe (or syringe cartridge) to another syringe, please explain why (select all that apply):**
☐ This is how I was taught to prepare injectable medications that come in certain syringes or cartridges
☐ Too hard to read the dose increments on the syringe from which the medication is withdrawn
☐ Need to dilute the drug before administration
☐ Cannot locate the designated cartridge holder to administer the medication
☐ The syringe does not have a needleless luer connection and/or has a needle that cannot be removed†
†Please list the drug(s) in syringes that do not have a luer connection: _____
☐ Other (please specify):_____

3 How often do you dilute IV push medications when they come in single-dose vials, multiple-dose vials, commercially available prefilled syringes, or pharmacy-prepared syringes? Which medications are being diluted?

Available Form	Never	Rarely‡	Some-times‡	Often‡	Always‡	‡Which medications are you diluting?
Single-dose vials						
Multiple-dose vials						
Commercially available prefilled syringes						
Pharmacy-prepared prefilled syringes						

If you never dilute IV push medications, skip to question 6.

4 How often do you use a prefilled 0.9% sodium chloride flush syringe (commercially available or pharmacy-prepared) to dilute, measure, and administer an IV push medication?
☐ Never ☐ Rarely§ ☐ Sometimes§ ☐ Often§ ☐ Always§
§Please describe the process:_____

5 Please explain why you dilute IV push medications (select all that apply):
☐ Medication dose/volume is difficult to measure without dilution
☐ To relieve anticipated discomfort at the injection site during administration
☐ Afraid of extravasation (e.g., vesicant drug, small IV access/delivery device)
☐ To administer the dose slowly to avoid untoward effects; small volume of the dose makes slow administration very difficult
☐ Other (please specify): _____

6 How often do you label IV push syringes that are self-prepared away from the patient's bedside?
☐ Never‖ ☐ Rarely‖ ☐ Sometimes‖ ☐ Often‖ ☐ Always ☐ Comments: _____

‖If you label self-prepared IV push syringes away from the patient's bedside less than 95% of the time, please explain why (select all that apply):
☐ No labels available
☐ Too time consuming
☐ Not necessary when I prepare only one medication
☐ Not necessary when I prepare only one syringe
☐ Emergency situation
☐ Not an expectation to label self-prepared syringes in my facility

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> Survey—continued from page 4

☐ Not necessary because I can distinguish between syringes by visual appearance or location[1]

[1]**Please explain how you distinguish between syringes when moving to a patient's bedside (select all that apply):**

- ☐ I hold the syringes in different hands
- ☐ I separate the syringes in different clothing pockets
- ☐ I place the syringes on a tray or sterile field in a certain way
- ☐ I mark one of the syringes containing a particular medication with a marker
- ☐ I know what is in each syringe because they contain different volumes
- ☐ I use different syringe sizes to tell them apart
- ☐ Other (please specify): _____

☐ Other (please specify):_____

7 Please indicate your agreement with the following statements related to IV push practices and the current drug shortage crisis.

STATEMENT: Given the current drug shortage crisis…	Disagree 1	2	3	4	Agree 5	Comments
IV push drugs are provided in unfamiliar formulations (concentrations, packages)						
I get less prefilled, ready-to-use syringes than previously						
I am required to prepare more IV push medications at the bedside						
I am giving more medications via IV push that were previously given as infusions						
Other (please specify):						

8 Please indicate how you learned about the following practices (select all that apply):

Learning methods	Practices: Administer IV push medications	Practices: Dilute IV push medications	Comments
During training, in professional school			
During orientation (first professional position)			
During orientation (current position)			
On-the-job, outside of orientation			
Drug references			
Never had formal instruction on this practice			
Never dilute medications			
Other (please specify):			

9 How do you determine the rate of administration of an IV push medication (select all that apply)?

- ☐ Rate provided on the medication administration record (MAR) or in the electronic health record (EHR)
- ☐ Rate available in facility-specific guidelines
- ☐ I look it up each time in drug reference material
- ☐ I remember the rate from previous administration
- ☐ I administer all IV push drugs over a typical 2-5 minute timeframe
- ☐ Other (please specify): _____

10 How do you control how fast you are administering an IV push medication (select all that apply)?

- ☐ I use a wall clock, watch, phone, or other timing device
- ☐ I keep constant pressure on the plunger and administer the dose over the course of the desired timeframe
- ☐ I divide the total volume into incremental doses and administer those specific volumes over the course of the desired timeframe
- ☐ I administer small incremental volumes every so often during the desired timeframe
- ☐ I administer half of the dose at the beginning of the timeframe and the rest at the end
- ☐ Other (please specify): _____

11 Please select the categories that best describes your profession and work setting.

Profession: ☐ Nurse ☐ Advanced Practice Nurse ☐ Nurse Anesthetist ☐ Anesthesiologist ☐ Other Physician ☐ Physician Assistant
☐ Other (please specify): _____

Work setting: ☐ Critical Care Unit ☐ Medical-Surgical Unit ☐ Emergency Department ☐ Surgical Area (OR, PACU)
☐ Other (please specify): _____