July 2025 | Volume 23 ■ Issue 7

ISMP Institute for Safe Medication Practices
An ECRI Company

Nurse AdviseERR®
Educating the Healthcare Community About Safe Medication Practices

what's in a Name?

The "-peridone" drug stem name

Medications ending with the suffix "-peridone" are known as second generation antipsychotics (SGAs) which are commonly referred to as "atypical antipsychotics." The term "atypical" is used for these drugs because they do not cause the "typical" side effects as seen with first generation antipsychotic drugs. For example, SGAs have a decreased risk of severe extrapyramidal side effects (EPS), such as tardive dyskinesia or tremors. In addition, they treat both positive (hallucinations, delusions) and negative (i.e., flat affect) signs and symptoms of schizophrenia. Besides schizophrenia, SGAs are used to treat other psychiatric conditions such as bipolar disorder and as an adjunct in major depressive disorder. They work by partially blocking dopamine receptors and may also affect serotonin receptors. Common side effects of SGAs are weight gain and metabolic changes (e.g., insulin resistance, hyperglycemia, diabetes, lipid abnormalities).

There are a number of SGA drugs approved by the US Food and Drug Administration (FDA); however, there are only three SGAs with the "-peridone" drug stem (**Table 1**) and all three are available as oral tablets. Risperi**DONE** also comes as an oral solution that can be swallowed directly or mixed with water, coffee, orange juice, or low-fat milk but is incompatible with cola or tea.

Table 1. SGAs with the drug stem "-peridone" that are currently available in the United States.

Generic Name	Brand Name(s)	Formulation(s)
iloperidone	**FANAPT, FANAPT TITRATION PACK**	oral tablet
paliperidone	**ERZOFRI**	injection, monthly (IM)
	INVEGA	oral extended release tablet
	INVEGA HAFYERA	injection, every six months (IM)
	INVEGA SUSTENNA	injection, monthly (IM)
	INVEGA TRINZA	injection, every three months (IM)
risperi**DONE**	**PERSERIS**	injection, monthly (SUBQ)
	RISPERDAL	oral solution, oral tablet, oral disintegrating tablet
	RISPERDAL CONSTA	injection (IM)
	RYKINDO	injection (IM)
	UZEDY	injection, every one or two months (SUBQ)

Paliperidone and risperi**DONE** are also available as injectable formulations which can be given at different intervals (**Table 1**). The prescribed dose interval may vary based on initiation, maintenance, managing missed doses, and conversion between products. For formulations that are given intramuscularly (IM), check the prescribing information for specific preparation (use of needle that is provided) and administration instructions including injection site (e.g., gluteal, deltoid) which may vary by dose (e.g., initial, maintenance).

Two of the risperi**DONE** formulations are administered subcutaneously (SUBQ) and have unique specifications that need to be followed. For example, when administering Perseris,

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SAFETY wires

Never dilute a medication in a saline flush syringe. A physician ordered chemotherapy for a pediatric oncology patient in an outpatient infusion center. To mitigate the risk of chemotherapy-induced nausea and vomiting, the prescriber ordered doses of oral ondansetron and intravenous (IV) diphenhydr**AMINE**, along with as needed (PRN) doses of IV prochlorperazine. The nurse diluted the diphenhydr**AMINE** and prochlorperazine in separate manufacturer-prefilled 10 mL saline (0.9% sodium chloride) flush syringes and labeled them with the drug names. The nurse administered the diluted diphenhydr**AMINE** IV using an infusion pump and set aside the diluted prochlorperazine syringe in case it was needed.

Before her break, the nurse communicated the antiemetic plan during the handoff to another nurse. Upon returning, the nurse found that a different nurse had taken over. The primary nurse could not find the syringe containing the prochlorperazine, but its label was on the floor. The covering nurse told the primary nurse that the prescriber had ordered another antiemetic, aprepitant, which she administered. However, she used the syringe containing prochlorperazine to flush the line after administering the aprepitant, thinking it was normal saline. No patient harm was reported. During the event investigation, it was uncovered that nurses at this clinic were encouraged to dilute/reconstitute medications in manufacturer-prefilled saline flush syringes due to the nationwide fluid shortages.

This is not the first time that ISMP has received a report of this type of error. The ISMP *Safe Practice Guidelines for Adult IV Push Medications* discourages dilution or reconstitution of medications in commercially available, prefilled flush syringes that could be mistaken as plain saline. The US Food and Drug Administration (FDA) regulates commercially available

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the patient should be lying supine. The injection sites should be rotated; however, the patient may experience a lump at the injection site that can last for weeks. It is important not to rub the injection site and to avoid administering where sleeves, cuffs, belts, or waistbands may rub against the site. When administering Uzedy, resistance may be felt while injecting the drug. It is important not to use excessive force to push the medicine in faster. Please see the manufacturers' labeling for more details about administering these drugs.

Patients should be closely monitored for adherence, weight gain, and abnormal laboratory results such as elevated blood glucose, hemoglobin A1C, lipids, and prolactin. Encourage patients to report any signs of developing EPS such as shaking, restlessness, stiffness; or more severe, involuntary movements such as lip and tongue smacking. Finally, these drugs have a *Boxed Warning* indicating there is an increased risk of mortality in elderly patients with dementia-related psychosis and are not approved for use in this patient population.

Delay in emergency medication delivery caused by syringe design

A prescriber ordered atropine for a patient during a code. The nurse obtained the 1 mg/10 mL atropine injection (by Amneal) from the code tray, which came in a package of 5 single-dose glass syringes (**Figure 1**). When attempting to remove the luer cover/cap (**Figure 2**), the nurse inadvertently twisted off the luer lock connection, which was overlaid onto a slip-tip connection. The nurse was unable to replace the luer lock connection and could not administer the medication to the patient through the intravenous (IV) line via a needleless luer connector. The nurse tried using a second syringe and the same thing occurred. The nurse called the pharmacist who delivered a different manufacturer's atropine syringe and the nurse was able to administer it to the patient. This initial failed attempt to use the first two syringes resulted in a delay of emergent treatment. Due to concerns with the syringe design, the hospital removed this product from the organization.

Figure 1. Carton of 5 atropine sulfate injection (1 mg/10 mL) syringes by Amneal.

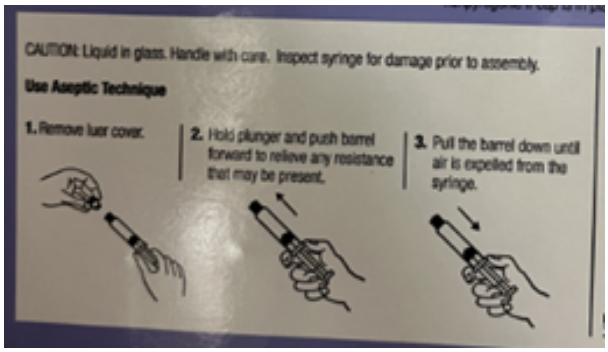

Figure 2. Directions included in the cartons containing 5 syringes do not warn against twisting the cap off.

Amneal also provides these syringes in cartons containing 24 single-dose syringes. Unlike the 5-syringe carton, the label on the 24-syringe pack has specific instructions on how to remove the luer cover/cap by carefully tilting it back and forth (DO NOT TWIST CAP) until the cap disconnects and then pull the cap off in a straight upward direction to remove it (**Figure 3**, page 3).

In another case, a patient in labor who was receiving oxytocin and an epidural infusion, began experiencing hypotension and fetal deceleration. The prescriber ordered **EMERPHED** (e**PHED**rine) 10 mg IV as needed (PRN) for hypotension. The nurse removed an Emerphed 25 mg/5 mL prefilled syringe (by Nexus, packaged in a BD Hypak glass syringe) from the automated dispensing cabinet (ADC). She removed the cap (**Figure 4**, page 3) and connected it to the patient's needleless IV connector but could not push any medication out of the syringe. She removed another syringe

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prefilled syringes of saline and heparin as devices, not as medications. These devices have been approved for the flushing of vascular access devices but have NOT been approved for reconstituting or diluting medications to be subsequently administered IV push. Organizations should NOT adopt this practice, even during shortages. Notify nurses of this risk and ensure policies and practices align with ISMP's guidelines.

Label design may result in incorrect dose. A nurse reported concerns with diaze**PAM** 10 mg/2 mL prefilled syringes by Natco. The graduated markings with the dose volume are printed on a label (i.e., sticker) that is placed onto the syringe. This sticker also acts as a tamper-evident seal that breaks when practitioners remove the syringe cap. Since the tamper-evident mechanism and the graduated markings are on the same sticker, it was thought that when the nurse twisted the syringe cap, the sticker shifted, and the syringe markings moved (**Figure 1**). The nurse who submitted the report was concerned that this could result in a practitioner preparing an inaccurate dose. In this case, the nurse used an empty syringe to draw up the

Figure 1. After a nurse removed the cap, she noticed that the label with the graduated markings was shifted on the diaze**PAM** 10 mg/2 mL prefilled syringe (right), so she prepared the patient's dose in another syringe. (The syringe on the left is used for comparison.)

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from the ADC and tried again. The same thing occurred. When she removed the syringe from the patient's port, it looked like the end was clogged with a piece of plastic. She obtained a third syringe, and when removing the cap, the entire luer lock connection pulled off the syringe, revealing a slip-tip (**Figure 5**). The nurse tried to connect the slip-tip to the patient's IV port, but the plunger could not be depressed. The IV port began leaking after this attempt. The nurse called the anesthesiologist to the bedside. The anesthesiologist had e**PHED**rine from a different manufacturer and was able to administer it. Although the dose was administered 10 minutes after it was ordered, the patient was not harmed by the delay.

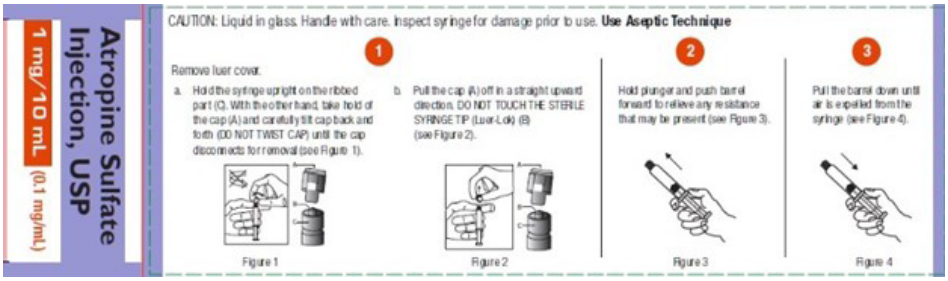

Figure 3. Instructions on a carton containing 24 single-dose syringes of Amneal's 1 mg/10 mL atropine injection state to pull the cover/cap off in a straight upward direction and "DO NOT TWIST CAP."

Another organization reported the same issue of not being able to administer Emerphed (by Nexus) from the prefilled syringe due to the BD Hypak glass syringe design. We shared this with the manufacturers and the US Food and Drug Administration (FDA). We have warned about medications in glass syringes that are incompatible with needleless connectors several times over the last few years and have called for syringe manufacturers to make changes to the product design to enhance compatibility, particularly in emergent situations that could potentially result in serious harm.

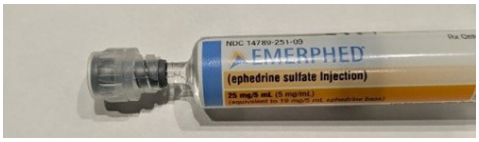

Figure 4. When the gray cap is removed from the e**PHED**rine 25 mg/5 mL prefilled syringe, there is a luer lock connector that covers a slip-tip syringe connector.

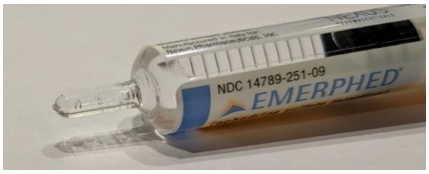

Figure 5. The nurse could not administer medication from the slip-tip connector on the e**PHED**rine glass syringe after the luer connection had come off.

We recommended that Amneal update the package labeling on the carton that contains 5 atropine syringes to instruct users how to remove the cap properly. They told us they have revised the carton label to provide more detailed instructions and pictorials specifically stating, "DO NOT TWIST CAP" so that all Amneal atropine sulfate injection labels will now have the same warning.

BD's Hypak syringes are used by other companies, so other issues may arise with other products. To address user error, BD has redesigned their syringe. In fact, in November 2024, Nexus began distributing Emerphed 5 mL prefilled syringes using the new BD syringe. However, products using the original design may still be on the market. Nexus is also transitioning their 10 mL prefilled syringe to the newly redesigned BD syringe. Additionally, they have updated the package insert instructions to clarify that the proper way to remove the cover is to **twist off the cap** (do not pull), and sent a notice to customers that depicts these instructions (**Figure 6**).

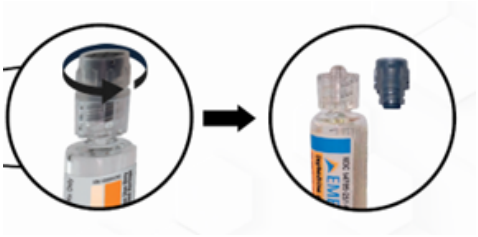

Figure 6. Practitioners must twist (not pull) the gray cap off to remove it so the luer connector is not improperly removed and the Emerphed can be administered without delay.

If your organization purchases any of these products, ensure staff are aware of how to remove the luer cover properly. Consider applying auxiliary labels with a warning or purchasing the product from an alternative manufacturer until this issue is resolved. Continue to report any issues to the manufacturers, FDA, and ISMP.

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patient's dose from the prefilled syringe to measure the dose.

We reached out to Natco to notify them of this concern. They stated that they have completed an investigation and did not identify any labeling defects. They have not received additional reports of this issue. We do not recommend transferring the syringe contents to another syringe as this defeats the safety of using a ready-to-use product. Notify staff of this risk and have them visually inspect the label markings prior to use. If the label is twisted, do not use the product. Report any issues to the manufacturer, the US Food and Drug Administration (FDA), and ISMP.

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Editors: Ann Shastay, MSN, RN, AOCN; Shannon Bertagnoli, PharmD; Jana O'Hara, MSN, RN, CPHQ, CPPS. ISMP, 3959 Welsh Road, #364, Willow Grove, PA 19090. Email: ismpinfo@ismp.org; Tel: 215-947-7797.