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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 "-nal-" drug stem name

Medications that have the "-nal-" stem belong to the opioid agonist/antagonist drug class. There are seven single-agent products that fall into this class of drugs (**Table 1**) that are approved for use in the United States by the US Food and Drug Administration (FDA). In general, these drugs reverse the effects of opioids but have different mechanisms of action and different indications. There are other opioid agonists in this drug class that do not contain the "-nal-" stem as well as combination products, neither will be discussed here.

Table 1. List of drugs with the "-nal-" stem available in the United States.

Generic Name	Brand Name(s)	Indication	Route
methylnaltrexone	**RELISTOR**	opioid-induced constipation	oral, subcutaneous
nalbuphine	n/a	pain	intramuscular, intravenous, subcutaneous
naldemedine	**SYMPROIC**	opioid-induced constipation	oral
nalmefene	**OPVEE**, **ZURNAI** (FDA approved August 2024)	opioid overdose	intramuscular, intravenous, nasal, subcutaneous
naloxegol	**MOVANTIK**	opioid-induced constipation	oral
naloxone	**KLOXXADO**, **NARCAN** (OTC), **REXTOVY** (FDA approved 2024), **REZENOPY**, **RIVIVE** (OTC), **ZIMHI**	opioid overdose	intramuscular, intravenous, nasal, subcutaneous
naltrexone	**VIVITROL**	opioid-use disorder	intramuscular, oral

The most common group of opioid antagonists displace the effects of opioids by crossing the blood-brain barrier and binding to the opioid receptors in the brain, blocking or reversing the effects of an opioid overdose. Currently, there are two single-agent opioid overdose reversal medications approved for use in the United States. There are three opioid antagonists approved for the treatment of opioid-induced constipation. These medications are called peripheral opioid receptor antagonists and work by blocking the effects of opioids in the gastrointestinal tract promoting normal bowel function. The opioid partial agonist is used to treat moderate to severe pain in pre/postoperatively and in labor and delivery cases where other opioids are insufficient. In addition, there is an opioid antagonist that is indicated for the treatment of opioid-use disorder which is used to reduce opioid withdrawal symptoms.

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SAFETY wires

Contaminated WG Critical Care calcium gluconate 2,000 mg/100 mL bag. A hospital reported sterility concerns with a calcium gluconate 2,000 mg/100 mL injection bag manufactured by WG Critical Care (NDC 44567-621-24, lot number 24Y00103, expiration date April 2027). A nurse went to remove a patient's dose from the automated dispensing cabinet (ADC) and, upon removing the overwrap, observed a floating black substance resembling mold inside the sealed, unopened inner bag (**Figure 1**). The nurse never spiked or administered the product. It was immediately sequestered and reported to the pharmacy and charge nurse. The hospital returned the bag to WG Critical Care for further investigation. The pharmacy removed all products with this lot number across the health system and has transitioned to an alternative manufacturer.

Figure 1. A black substance was found inside a sealed, unopened bag of calcium gluconate 2,000 mg/100 mL.

We have reported this issue to the US Food and Drug Administration (FDA) and the manufacturer. The manufacturer immediately initiated an investigation. They told us they completed a comprehensive investigation and attributed the contamination to a microchannel defect at the seal between the tubing and the bag, compromising the product's sterility. The manufacturer confirmed that the bag

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Opioid Overdose Reversal

The opioid antagonists used to treat an overdose are usually administered intranasally in the outpatient setting and rapidly reverse the overdose. If no response occurs within two or three minutes of administration, then a second dose may be given. Nalmefene has a longer duration than naloxone and can be used to reduce the use of naloxone infusion, but it can prolong the effect of opioid withdrawal. Naloxone also is available as an injection for intramuscular, subcutaneous, or intravenous (IV) use, and an IV infusion is sometimes used due to its quicker onset of action. Patients may wake up with acute withdrawal syndrome, which includes agitation, nausea, vomiting, diarrhea, and goosebumps. Common side effects from these products may include nasal congestion, headaches, muscle pain, anxiety, and shortness of breath.

Opioid-Induced Constipation

The opioid antagonists used to treat opioid-induced constipation block the effects of opioids in the gastrointestinal tract but do not provide pain relief since they do not cross the blood-brain barrier. Naloxegol and naldemedine are oral medications while methylnaltrexone is available as an oral formulation or a subcutaneous injection. The injectable formulation is faster and more effective, while the oral formulation is convenient for long-term use. Opioid-induced constipation is often a debilitating side effect of chronic opioid use. Common side effects of opioid antagonists include stomach pain, diarrhea, gas, nausea, vomiting, and excessive sweating. These drugs should be avoided in patients with a bowel obstruction or a history of it.

Opioid-Use Disorder

The opioid antagonist used to treat opioid-use disorder is available in different formulations. Oral naltrexone should be administered once daily, or an extended-release intramuscular injection can be given every four weeks. Common side effects are blurred vision, loss of appetite, irritability, and constipation. Alcohol should be avoided when taking this medication.

Nilotinib formulations are NOT interchangeable

On November 14, 2024, Azurity Pharmaceuticals announced the approval of **DANZITEN** (nilotinib tartrate), indicated for adults with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in the chronic phase (CP) and accelerated phase (AP) of Ph+ CML resistant to or intolerant to prior therapy that included imatinib. Danziten is available in blister packs of 71 mg or 95 mg tablets, which must be swallowed whole and may be taken with or without food. Danziten is NOT approved for pediatric use.

TASIGNA (nilotinib hydrochloride), manufactured by Novartis, is approved for the same indications as Danziten but for both adult and pediatric patients 1 year of age and older. Tasigna is available in different strengths—bottles containing 50 mg capsules or blister packs containing 150 mg or 200 mg capsules—and a different salt form than Danziten. Due to Tasigna's increased bioavailability when taken with food, it has a *boxed warning* to avoid food 2 hours before and 1 hour after taking the medication, as the increased absorption increases the risk of a significantly prolonged QT interval. However, according to the Tasigna prescribing information, the capsules may be opened and dispersed in a small amount (one teaspoon) of applesauce.

The distinct salts of the two available nilotinib formulations, nilotinib ***tartrate*** (Danziten) and nilotinib ***hydrochloride*** (Tasinga) result in important differences in dosage, administration precautions, and even adverse effect risk. Both formulations have a *boxed warning* for QT

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was contaminated with mold, and this was an isolated event. This incident underscores how critical it is for end users to stay vigilant in reviewing product integrity and escalate potential safety issues. If your organization purchases calcium gluconate 2,000 mg/100 mL from WG Critical Care, review your inventory and ensure end users are aware of this concern. According to instructions on the bag label, practitioners should check for leaks by squeezing the container. If potentially impacted product is found, sequester it and report it to the manufacturer, FDA, and ISMP. Remind staff to visually inspect all medication injectable solutions for particulate matter, discoloration, and potential contaminants prior to use.

Hazard! Broselow Rainbow Tape contains incorrect information. The Broselow Rainbow Tape is a tool used during emergencies that has color zones with pre-calculated information for medication dosages, equipment sizes, and other procedures based on the child's height, measured using the tape. ECRI recently published an alert stating that on May 15, 2025, AirLife released an urgent medical device recall for its branded version of the Broselow Rainbow Tape product code 7700REA. They have notified customers that "AirLife brand, 2025 Edition, and 36-23446 Rev 2 Print Version" Broselow Rainbow Tape has been manufactured with incorrect information. The letter details the following:

- The values for the **Red zone** (6 to 11 months, 8 to 9 kg) in the Cardioversion/Defibrillation section contain the incorrect Joules. See Image B in the letter, which shows the incorrect information highlighted. Using the correct Joule level is crucial for effective cardioversion and defibrillation while minimizing the risk of harm to the patient. Shocking an 8 to 9 kg patient with an excessive dose of Joules may cause significant harm, including burns, heart damage, and potential cardiac arrest. **The correct Cardioversion/Defibrillation information for a 6 to 11 month patient (8 to 9 kg) in the Red zone of the Broselow Rainbow Tape is:**
  - **Synchronized Cardioversion 1st Dose should be 9 Joules**

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prolongation and sudden death with specific monitoring recommendations and the need to avoid additional QT prolonging agents or strong CYP3A4 inhibitors.

It is critical to note that these products are not interchangeable and have very different dosing recommendations (**Table 1**). Because of this, there is a risk of under- or overdose and patient harm if the wrong product is selected for the ordered dosing regimen. The risk of a selection error may be increased if practitioners order the drug only by the generic name without the salt form.

Table 1. Recommended adult dosing for Danziten and Tasigna.

Approved indications for adults	Danziten dosage (with or without food)*	Tasigna dosage (on an empty stomach)*
Newly diagnosed Ph+ CML-CP	142 mg every twelve hours	300 mg every twelve hours
Resistant or intolerant Ph+ CML-CP and CML-AP	190 mg every twelve hours	400 mg every twelve hours

*Doses may be modified or reduced based on organ function, cardiac monitoring, laboratory values, or concomitant medications.

When reviewing a patient's medication history, it is important for nurses to understand the differences between these drugs to ensure the correct formulation and brand name is noted in the medical record. ISMP has notified the US Food and Drug Administration (FDA) of these concerns. Ensure that the patient knows the correct formulation they are taking, whether it should be taken with or without food, and reinforce the correct dosing instructions, especially if the patient is directed to take a reduced or alternate dose than what is included in the blister pack.

Special Announcements

Work for ISMP

ISMP is looking for a ***Medication Safety Specialist-Education*** who will be responsible for the coordination and implementation of our educational programming. Visit: *Job Opportunities*.

Apply for a JUST CULTURE scholarship

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

Survey on IV Push Medications

Med Safety Board, an ISMP company, is conducting a short survey to reassess current practices and safety risks with intravenous (IV) push medications. Please take 5-10 minutes to complete the survey by **September 30, 2025**. Thank you for your participation!

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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.

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- **Synchronized Cardioversion 2nd Dose should be 18 Joules**
- **1st defibrillation should be 18 Joules**
- **2nd defibrillation should be 36 Joules**
- **3rd defibrillation should be 54 Joules**

- The information for sodium bicarbonate in the **Orange zone** of the tape (7 to 9 years, 24 to 28 kg) is incorrect. See Image C in the letter, which shows the incorrect information highlighted. The incorrect concentration listed may lead to overdosing the patient and may cause metabolic alkalosis, electrolyte imbalances, tissue damage, and potentially worsen respiratory status. **The correct sodium bicarbonate concentration for the Orange zone (7 to 9 years, 24 to 28 kg) should be 27 mEq (27 mL).**

- The information for sodium bicarbonate concentration in the **Grey zone** of the tape (less than 3 months, 3 to 5 kg) is incorrect. See Image D in the letter, which shows the incorrect information highlighted. The incorrect concentration listed may lead to underdosing the patient and may cause reduced myocardial contractility, decreased response to vasopressors, and increased risk of dysrhythmia. **The correct sodium bicarbonate concentration for the Grey zone (less than 3 months, 3 to 5 kg) should be 8.4%.**

Conduct a thorough search and check the inventory in all locations where this product may be used. Ensure all Emergency Response Team members in your organization are notified. If impacted product is identified, immediately discontinue use and destroy affected product. Complete the Response Form and Certificate of Destruction Form provided in the recall letter, and return the forms to AirLife, who will provide replacement product. Educate practitioners about this safety concern and the actions you have taken. Report issues to the US Food and Drug Administration (FDA) and ISMP.