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ISMP Institute for Safe Medication Practices
An ECRI Company

Community/Ambulatory Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

More potential confusion–another nilotinib product hits the market

Problem: In our February 2025 article, Nilotinib Formulations–Danziten and Tasigna–Are Not Interchangeable, we discussed the potential confusion between **DANZITEN** (nilotinib tartrate) and **TASIGNA** (nilotinib hydrochloride). Although both products are nilotinib formulations, they are different salt forms, are not interchangeable, and have significantly different dosing recommendations (**Table 1**). These differences pose a risk of underdose or overdose, potentially leading to patient harm if the wrong product is selected. Also, 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, or it may significantly prolong the QT interval. Danziten can be taken with or without food.

Table 1. Recommended adult dosing for nilotinib products.*

Medication	Newly diagnosed Ph+ CML-CP	Resistant or intolerant Ph+ CML-CP and CML-AP
Danziten	142 mg every 12 hours	190 mg every 12 hours
Tasigna	300 mg every 12 hours	400 mg every 12 hours
Nilotinib D-Tartrate	300 mg every 12 hours	400 mg every 12 hours

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

New Nilotinib Product

To complicate the landscape further, another nilotinib product, nilotinib d-tartrate, was approved by the US Food and Drug Administration (FDA) in February 2025 and is now available. While there are overlapping characteristics among the three nilotinib products (**Table 2**, page 2), it is critical to understand that they are not interchangeable. Like Danziten and Tasigna, nilotinib d-tartrate is indicated for adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase (CP) and for adults with CP or accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib. Neither Danziten nor nilotinib d-tartrate is approved for use in pediatric patients, which is different than Tasigna which can be used to treat pediatric patients. While the dosing recommendations for nilotinib d-tartrate are the same as the Tasigna adult dosing—300 mg every 12 hours for adults with newly diagnosed Ph+ CML-CP and 400 mg every 12 hours for adults with resistant or intolerant Ph+ CML-CP and CML-AP—the products are not interchangeable.

It is important to note that nilotinib d-tartrate carries the same Boxed Warning as Tasigna to avoid food 2 hours before and 1 hour after taking the medication, or it may significantly prolong the QT interval.

Confusion Among Nilotinib Products

As highlighted in our February 2025 article, it is crucial for drug information vendors and electronic health record (EHR) vendors to clearly differentiate these products. Unfortunately, we recently received a report that indicates the electronic listing of these drugs may not always be clear. A

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SAFETY briefs

Confirm the expiration date on the Abrysvo vial and kit. The Pfizer **ABRYSVO** (respiratory syncytial virus [RSV] vaccine) vial and syringe presentation is supplied in a carton that contains kits. Each kit includes a vial of lyophilized antigen component (powder), a prefilled syringe containing sterile water diluent, and a vial adapter. A pharmacist reported concerns that the expiration date most visible on the kit (**Figure 1**) is NOT the

Figure 1. The expiration date most visible on the Abrysvo kit (9/1/2028) is for the vial adapter and NOT the actual vaccine expiration date.

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IMPORTANT! Read and utilize the Community/Ambulatory Care Action Agenda

Items from the **September – December 2025** issues of the ***ISMP Medication Safety Alert! Community/Ambulatory Care*** newsletters have been selected and prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, a few recommendations to reduce the risk of errors, and the issue date to locate additional information. The **Action Agenda** is available as an Excel file here.

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Table 2. Product characteristics of the available nilotinib products.

Formulation Characteristics	Nilotinib D-Tartrate	Danziten	Tasigna
Indications	■ Newly diagnosed Ph+ CML-CP ■ Resistant or intolerant Ph+ CML-CP and CML-AP	■ Newly diagnosed Ph+ CML-CP ■ Resistant or intolerant Ph+ CML-CP and CML-AP	■ Newly diagnosed Ph+ CML-CP ■ Resistant or intolerant Ph+ CML-CP and CML-AP
Strengths	■ 50 mg ■ 150 mg ■ 200 mg	■ 71 mg ■ 95 mg	■ 50 mg ■ 150 mg ■ 200 mg
Dosage forms	■ Capsule, oral	■ Tablet, oral	■ Capsule, oral
Patient populations	■ Adults	■ Adults	■ Adults ■ Pediatric patients 1 year of age and older
Administration	■ Take on an empty stomach ■ Avoid food 2 hours before and 1 hour after dose	■ Take with or without food	■ Take on an empty stomach ■ Avoid food 2 hours before and 1 hour after dose
Boxed warnings	■ QT prolongation and sudden deaths ■ Avoid food 2 hours before and 1 hour after dose	■ QT prolongation and sudden deaths	■ QT prolongation and sudden deaths ■ Avoid food 2 hours before and 1 hour after dose

pharmacy was ordering Danziten, but the wholesaler listed nilotinib tartrate, which is the salt form of Danziten, as 50 mg, 150 mg, and 200 mg capsules, which are the dosage strengths of Tasigna (nilotinib hydrochloride) and nilotinib d-tartrate. The pharmacy contacted the wholesaler who informed them that it is the listing for nilotinib d-tartrate from the manufacturer Cipla. Cipla shared, "Our product is Nilotinib Tartrate, approved referencing Tasigna, based on an alternative salt. It matches Tasigna in most aspects, including strength and dosage. Danziten also uses the tartrate salt but differs in strength and other characteristics. It was not referenced in our filing." This has great potential for confusion and error.

Safe Practice Recommendations: ISMP has notified FDA of this concern and recommends that drug information vendors and EHR vendors clearly differentiate these products and ensure they are not interchangeable in electronic systems. Medical offices, clinics, and pharmacies should evaluate how these drugs are displayed in their electronic systems. Implement clinical decision support with dose range checking and warnings (e.g., avoid food 2 hours before and 1 hour after administering Tasigna or nilotinib d-tartrate). Educate staff and patients about the non-interchangeability of these products and ensure the correct product is confirmed prior to dispensing and administration. During patient education, emphasize which product, including the brand name if applicable, the patient is taking, whether it should be taken with or without food, and the correct dosing instructions.

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expiration date of the actual vaccine (vial); it is the expiration date printed on the vial adapter. The vaccine vial may expire much sooner (**Figure 2**). If a practitioner does not look at the expiration date on the vaccine vial prior to administration, there is a risk that a patient may receive an expired vaccine.

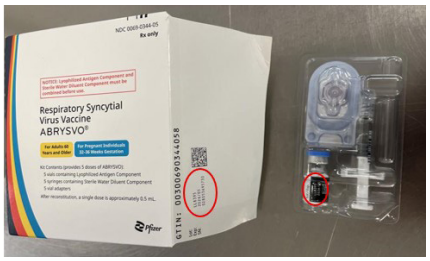

Figure 2. The expiration date of the vaccine found on the Abrysvo outer carton and vial may be much sooner (5/2026) than the expiration date on the kit label (see Figure 1, page 1).

We have reached out to Pfizer to notify them of this concern. Organizations should develop a plan to ensure that practitioners know where to find the correct vaccine expiration date. The hospital that reported this issue is adding a sticker with the vial's expiration date to the outside of each kit, which is a manual process and not ideal.

HIGH-ALERT

Demo IUD inserted vaginally. A prescriber intended to insert a **MIRENA** (levonorgestrel) intrauterine device (IUD) into a patient at the physician's office. After inserting the device vaginally, the prescriber identified that they had inadvertently inserted a demonstration (demo) **KYLEENA** (levonorgestrel) IUD. Bayer makes both products. Immediately following insertion, the prescriber noticed during documentation that the demo device was used. The prescriber notified the patient of the error, removed the demo device, and inserted the correct Mirena IUD. There was no reported harm.

Prescribers do not insert IUDs frequently in this physician's practice. For educational purposes, demo IUDs were stored on the counter in the procedure room. The IUDs that contain the actual medication were in a locked cabinet also in the procedure room. The Kyleena demo IUD was packaged in a non-sterile, sealed, tear-apart package (**Figure 1**, page 3). The front of the package

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Top 10 Health Technology Hazards for 2026

ECRI recently released its Top 10 Health Technology Hazards for 2026. This annual report identifies the potential sources of danger involving the use of medical devices and systems that ECRI believes warrant the greatest attention this year and offers practical recommendations for reducing risks. Since its creation in 2008, this report has supported healthcare settings and manufacturers in addressing healthcare technology risks that can impact patients and staff. This year's list includes:

1. The misuse of AI chatbots in healthcare
2. Unpreparedness for a "digital darkness" event
3. The growing challenge of combating substandard and falsified medical products
4. Recall communication failures for home diabetes management technologies
5. Tubing misconnections remain a threat amid slow ENFit and NRFit adoption
6. Underutilizing medication safety technologies in perioperative settings
7. Deficient device cleaning instructions continue to endanger patients
8. Cybersecurity risks from legacy medical devices
9. Technology designs or configurations that prompt unsafe clinical workflows
10. Water quality issues during instrument sterilization

Welcome our new staff members

Director of Med Safety Board

Gretchen Brummel, PharmD, BCPS, joined our team as Director of Med Safety Board, an ISMP Company. Gretchen is a pharmacist and healthcare leader with expertise in safety, pediatric pharmacotherapy, digital and rural health, and disaster preparedness. She most recently served as Director of the Professional Experience Program at a college of pharmacy, leading experiential learning. Her prior roles include executive and clinical leadership at a performance improvement organization, a global information services company, and a quaternary medical center.

Medication Safety Specialist, Education

Kimberly West, MSN-Ed, RN, CHSE, joined ISMP as the Medication Safety Specialist for Education. Kimberly has worked in various hospital settings and is a Certified Healthcare Simulation Educator (CHSE). Most recently, she was an Assistant Professor of Nursing and Simulation Champion for Rasmussen University School of Nursing where she developed faculty onboarding; mentored faculty and students; was the course lead and exam coordinator; helped with curriculum design; and was involved in the building of a new simulation lab at the university.

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has a warning, "STOP, NOT FOR USE IN HUMANS," and the back has a warning, "STOP NON-STERILE NOT FOR USE IN HUMANS."

Due to how these warning messages are composed and the placement of the "non-sterile" warning on the back of the demo device package, a practitioner could easily mistake the demo for a sterile IUD that contains actual medication. There is also concern with negative warning statements that the practitioner may only see the active action (FOR USE IN HUMANS) and miss the "NOT" in the beginning part of the statement, especially if the label is obstructed, or the statement is separated on to two lines. The practice has since removed demo devices from the office.

Figure 1. Front (left) and back (right) sides of the demo Kyleena IUD, which comes in a non-sterile, sealed, tear-apart package resembling actual medication.

Manufacturers should package demo products to look distinctly different than the actual product and should prominently indicate on the label that they are for demonstration purposes only.

Store demo products that are used in simulation training separately in a training area and away from medication storage areas or patient care areas (e.g., procedure rooms), where they could be mistaken for actual medications. Affix auxiliary labels on all simulation supplies (e.g., For Demonstration Only, Education only). When demo devices are in use, establish a process for educators to account for every demo device used during training simulations. If you suspect that any training products may have been or were almost administered to a patient, please report it to ISMP, even if the event did not harm the patient.

Special thanks to our 2025 MSOS Member Briefings Presenters

The Medication Safety Officers Society (MSOS) holds Member Briefings every other month on various medication safety topics. The MSOS Member Briefings are webinars that feature three 10-minute presentations from volunteer MSOS members who highlight a project, initiative, or relevant medication safety topic. The goal is for participants to take the information presented and use it to implement similar medication safety initiatives within their own organization. At each Member Briefing, ISMP President Rita Jew also provides an update on ISMP activities. Please let us know (ismpinfo@ismp.org) if there is a medication safety topic you would like to present (or see presented) during a 2026 MSOS Member Briefing. We hope others can join us as presenters in 2026! To join the MSOS and attend the Member Briefings, visit: www.medsafetyofficer.org/user/register. MSOS membership and the 2026 Member Briefings are **FREE**.

Production of the MSOS Member Briefings would not be possible without the assistance of voluntary MSOS member presenters. ISMP sincerely thanks all of the 2025 presenters sharing their knowledge and expertise in pursuit of our mission to advance and encourage excellence in medication-use safety.

Thank You!

- **Rukhsar Banu**, PharmD; University Health, San Antonio, TX
- **Erica Brock**; AdventHealth, Orlando, FL
- **Stacy Carson**, PharmD, BCPS, FISMP; AdventHealth, Orlando, FL
- **Loriann De Martini**, PharmD, MPH, BCGP; California Society of Health-System Pharmacists, Sacramento, CA
- **Michael Elduff**; AdventHealth, Orlando, FL
- **Stacie Ethington**, MSN, RN; Nebraska Medicine, Omaha, NE
- **Crystal Franco-Martinez**, PharmD, BCPS; University Health, San Antonio, TX
- **Erica Fredette**, PharmD, BCPS, CPPS; South Shore Health, South Weymouth, MA
- **Liz Ford**, PharmD, MS, FISMP, CPPS; UK HealthCare, Lexington, KY
- **Sloane Hoefer**, PharmD, BCPS; Nebraska Medicine, Omaha, NE
- **Nicole Huber**, RN, RRT; AdventHealth, Orlando, FL
- **Viktoriya Ingram**, PharmD, FISMP; Washington Health, Fremont, CA
- **Kevin McQueen**, MHA, RRT, RRT-ACCS, CPPS, FAARC; UC Health Memorial Hospital, Colorado Springs, CO
- **Abhi Mehta**, PharmD, MS, MBA; Salinas Valley Health, Salinas, CA
- **Brad Schwartz**, BSPharm, BCPS; Avita Health System, Bucyrus, OH
- **Kara Thornton**, PharmD, MEd, CPPS; UVA Health, Charlottesville, VA
- **Madison Yates**, PharmD, BCACP, CPP; Cone Health, Greensboro, NC

MSOS
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