

April 17, 2013

Confusion regarding the generic name of the HER2-targeted drug KADCYLA (ado-trastuzumab emtansine)



On February 22, 2013, the US Food and Drug Administration (FDA) approved **KADCYLA** with the generic name of **ado-trastuzumab emtansine**. Unfortunately, some confusion surrounding the drug's generic name exists.

The original generic name for Kadcylla, as established by the US Adopted Name (USAN) Council in 2009, was trastuzumab emtansine. Given its similarity to the generic name for **HERCEPTIN** (trastuzumab) and the potential for confusion between the two medications, the FDA approved the addition of the contrived prefix “ado” to the generic name for Kadcylla. Thus the official FDA-approved generic name for Kadcylla is now ado-trastuzumab emtansine.

In the *ISMP Medication Safety Alert!* published on March 7, 2013, the Institute for Safe Medication Practices (ISMP) described the potential confusion between the two drugs due to the similarity in generic names, even with the prefix “ado.” Specifically, the official generic name, ado-

trastuzumab emtansine, may not be fully communicated when the drug is prescribed, fully displayed in automated systems, or may be read incompletely, thus creating a significant risk of being confused with trastuzumab.

Given that the dosing and treatment schedules for these drugs are quite different, confusion could lead to dosing errors and potential harm to the patient. For example, the recommended dose of ado-trastuzumab emtansine (Kadcyla) is 3.6 mg/kg given as an IV infusion every 3 weeks (21-day cycle) as a **SINGLE AGENT** until disease progression or unacceptable toxicity. Doses higher than that should not be given. However, trastuzumab (Herceptin) is prescribed in doses up to 8 mg/kg per loading dose, followed by a maintenance dose of 6 mg/kg every 3 weeks—about twice the maximum dose of Kadcylla.

Further, it has come to our attention that certain drug information content publishers have utilized the initial generic name of Kadcylla without the “ado” prefix. As such, certain drug information publications, compendia references, and

health information systems (e.g., wholesaler ordering, pharmacy ordering, and electronic health record systems) may display the generic name as “trastuzumab emtansine.” Users searching with the prefix “ado” may not find “ado-trastuzumab emtansine” in these publications or systems. As a result, healthcare providers may not be able to place orders for Kadcylla, prescribe the drug, or find drug information for Kadcylla, and patients may not receive proper therapy. Furthermore, even if the generic name is manually corrected in your information systems, routine automated updates from drug information content publishers that do not list the prefix “ado” may override and reverse the manual correction.

Thus, we advise healthcare practitioners to take these steps to avoid harmful errors:

- **Use the correct generic name.** Whether you are a healthcare practitioner, an author, editor, indexer, medical records librarian, or other health-related professional, use only the correct generic name listed with

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the prefix “ado” for Kadcyla, as used for all Kadcyla product labeling and packaging from the manufacturer, Genentech. (We understand that Genentech has alerted the FDA of the problem with the generic name, and a resolution is still pending.)

- **List by generic name.** List Kadcyla alphabetically by its generic name, using a dash between ado and trastuzumab (ado-trastuzumab emtansine).
- **Include brand and generic name.** Ideally, prescribers and other healthcare professionals should use the brand name and include the generic name of Kadcyla when communicating orders on preprinted order sets or in computerized order entry systems (prescriber and pharmacy). Such a redundancy can be helpful in reducing the risk of an error.

- **Differentiate generic names.** Proactively employ strategies to differentiate Kadcyla and Herceptin generic names, and warn against confusion in medication-related computer systems and guidelines.

- **Increase awareness.** Be aware of the potential for the generic name of Kadcyla to be listed both with or without the prefix “ado” in third-party publications and information systems, and on the Internet; amend search criteria accordingly.

ISMP has contacted major drug information vendors, including Medi-Span, Facts & Comparisons, Lexicomp, Multum, Gold Standard, UpToDate, Micromedex (Truven Health Analytics), and First Databank. At the time of publication of the Alert, only Micromedex was still using trastuzumab emtansine without the “ado” prefix and had not

confirmed its response to our request to add the prefix. Still, the generic name may continue to be seen without the prefix in some drug information resources and on the Internet. ISMP is also contacting major drug wholesalers to confirm the use of proper nomenclature.

Kadcyla, as a single agent, is indicated for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have received prior therapy for metastatic disease or developed disease recurrence during or within 6 months of completing adjuvant therapy. Kadcyla is associated with a Boxed Warning regarding the potential for hepatotoxicity, cardiac toxicity, and embryo-fetal toxicity. Additionally, the label warns that Kadcyla should not be substituted for or with trastuzumab.



The National Alert Network (NAN) is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The network, in cooperation with the Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP), distributes NAN Alerts to warn healthcare providers of the risk for medication errors that have caused or may cause serious harm or death. NCC MERP, ISMP, and ASHP encourage the sharing and reporting of medication errors both nationally and locally, so that lessons learned can be used to increase the safety of the medication use system.