U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Drug Safety Communications

FDA warns about potential medication errors resulting from confusion regarding nonproprietary name for breast cancer drug Kadcyla (ado-trastuzumab emtansine)

Safety Announcement

[5-6-2013] The U.S. Food and Drug Administration (FDA) is alerting health care professionals that the use of the incorrect nonproprietary name for the breast cancer drug Kadcyla (ado-trastuzumab emtansine) in some medication-related electronic systems poses a risk of mix-up with Herceptin (trastuzumab) and may result in medication errors. The dosing and treatment schedules for Kadcyla and Herceptin, another breast cancer drug, are quite different, so confusion between these products could lead to dosing errors and potential harm to patients.

The FDA-approved nonproprietary name for Kadcyla, ado-trastuzumab emtansine, should be used. However, some third-party publications, compendia references, health information systems (e.g., electronic health record systems and systems used for pharmacy prescription processing, wholesaler ordering, pharmacy ordering, etc.), and sites on the Internet are incorrectly using the United States Adopted Name (USAN), which is "trastuzumab emtansine," and omitting the "ado" prefix and hyphen. Use of this truncated version of Kadcyla's nonproprietary name may cause confusion with Herceptin (trastuzumab).

Health care professionals should use both the FDA-approved proprietary (brand) name Kadcyla and its nonproprietary name (ado-trastuzumab emtansine) when communicating medication orders, on preprinted order sets, and in computerized order entry systems. Such redundancy may help to reduce the potential for medication errors. Additionally, strategies should be employed to warn against confusion between Kadcyla (ado-trastuzumab emtansine) and Herceptin (trastuzumab) in medication-related computer systems.

It is important for drug information content publishers to identify drug products by the FDA-approved proprietary (brand) and nonproprietary names that are used in FDA-approved drug labels. This will help prevent medication errors and ensure adverse events are reported for the correct product.

No medication errors related to confusion between Kadcyla and Herceptin have been reported to FDA since approval of Kadcyla on February 22, 2013; however medication

errors did occur during the clinical trials that evaluated its safety and efficacy prior to approval.

Facts about Kadcyla (ado-trastuzumab emtansine)

- Kadcyla is used to treat HER2-positive breast cancer that has spread to other parts of the body in patients who have received prior treatment with Herceptin (trastuzumab) and a taxane chemotherapy.
- Kadcyla is made up of trastuzumab, an anti-HER2 therapy, connected to a drug called DM1 that interferes with cancer cell growth.

Information for Patients

- Talk to your health care professional if you have any questions or concerns about Kadcyla (ado-trastuzumab emtansine) or Herceptin (trastuzumab).
- Report medication errors and side effects from Kadcyla to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Additional Information for Health Care Professionals

- Be aware of the potential for the nonproprietary name for Kadcyla, ado-trastuzumab emtansine, to be listed both with and without the prefix “ado” in third-party publications, health information systems, and on the Internet.
- Use both “Kadcyla,” the FDA-approved proprietary (brand) name, and “ado-trastuzumab emtansine,” the product’s nonproprietary name, when communicating medication orders, on preprinted order sets, and computerized order entry systems (prescriber and pharmacy).
- Employ strategies to warn against confusion between Kadcyla (ado-trastuzumab emtansine) and Herceptin (trastuzumab) in medication-related computer systems.
- If the nonproprietary name for Kadcyla is incorrectly identified as “trastuzumab emtansine,” manually correct the nonproprietary name for Kadcyla to ado-trastuzumab emtansine in your information systems. Keep in mind that routine automated updates from drug information content publishers that do not list the prefix “ado” may override and reverse the manual correction.
- Kadcyla and Herceptin are ***not*** the same product. Kadcyla (ado-trastuzumab emtansine) should not be substituted for or used with Herceptin (trastuzumab). For a detailed comparison of these products, see the manufacturer’s website at http://www.kadcyla.com/pdf/medication-distinction-flashcard.pdf
- The recommended dose of Kadcyla is 3.6 mg/kg administered as a single agent by intravenous infusion every 3 weeks (21-day cycle). Doses greater than 3.6 mg/kg should not be administered. In contrast, the recommended dose of Herceptin is significantly higher, up to 8 mg/kg per loading dose, followed by a maintenance dose of 6 mg/kg every 3 weeks.

- Report medication errors and adverse events involving Kadcyla to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Background

FDA approved Kadcyla (ado-trastuzumab emtansine) on February 22, 2013, for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.

Medication errors involving Herceptin and Kadcyla occurred during the clinical trials that evaluated the safety and efficacy of Kadcyla. Four patients were administered Kadcyla (ado-trastuzumab emtansine) 6 mg/kg instead of the intended drug Herceptin (trastuzumab) 6 mg/kg. The recommended dose of Kadcyla is 3.6 mg/kg administered as a single agent by intravenous infusion every 3 weeks (21-day cycle). Doses higher than that should not be given. However, 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.

The original nonproprietary name for Kadcyla, as established by the United States Adopted Name (USAN) Council was “trastuzumab emtansine.” Given the similarity between the original nonproprietary name for Kadcyla as established by USAN and the nonproprietary name for Herceptin (trastuzumab) and the risk of confusion between the two drugs, FDA required the addition of the prefix “ado” followed by a hyphen to Kadcyla’s original nonproprietary name. The nonproprietary name for Kadcyla is ado-trastuzumab emtansine as reflected in FDA-approved prescribing information.