Cancer Care Ontario

Action Cancer Ontario

Kadcyla® Trastuzumab Emtansine Safety Reminder

With public funding for trastuzumab emtansine (Kadcyla®) in Ontario as of May 28, 2014, the use of this product is anticipated to increase. Cancer Care Ontario wishes to remind providers to remain vigilant against medication errors and to submit any near misses or actual errors that occur to Kathy Vu, Clinical Lead Safety Initiatives (Kathy.vu@cancercare.on.ca), the Institute for Safe Medication Practices (ISMP) Canada, or the National System for Incident Reporting (NSIR).

Trastuzumab emtansine (Kadcyla®) and trastuzumab (Herceptin®) have look alike/sound alike names. They are not the same product and are not interchangeable. The doses, treatment schedules and indications are different:

- Trastuzumab emtansine (Kadcyla®) is a combination of the trastuzumab monoclonal antibody and a highly toxic chemotherapy molecule
- The standard trastuzumab emtansine (Kadcyla®) dose of 3.6mg/kg body weight is much lower than the standard trastuzumab (Herceptin®) dose of 6mg/kg or 8mg/kg

There have been fatal reports[1,2,3] where the incorrect trastuzumab product was administered to patients with breast cancer in the clinical trials setting. A potential for error may occur during prescribing, preparation, or administration. An additional concern is the high risk of incorrect product selection between these two agents, as medications in computerized physician order entry (CPOE) systems are usually listed according to their generic name.

In accordance with Health Canada's recommendation, **The Systemic Treatment Program at Cancer Care Ontario recommends that:**

1. OPIS and other ST CPOE systems adopt the nomenclature 'Kadcyla trastuzumab emtansine' to differentiate this product from trastuzumab. This safeguard will help to avoid selecting the wrong product at the time of prescription ordering, preparation and administration
2. Apply a maximum dose cap for trastuzumab emtansine (e.g. 360 mg)
3. Education is provided to staff (physicians, pharmacists and nurses) to heighten awareness of the potential for error.
4. Store products separately in the Pharmacy Department
    - Consider storing trastuzumab emtansine in a separate container (e.g. zip-lock bag) and clearly affix with warning label (e.g. "Kadcyla® trastuzumab emtansine – substitution error may lead to harm")
    - Store trastuzumab emtansine away from trastuzumab supplies (consider storing separately from "working stock")
5. Consider implementing an independent double check if dealing with higher risk situation, either at administration or with preparation

[1] http://www.rochecanada.com/fmfiles/re7234008/Research/ClinicalTrialsForms/Products/ConsumerInformation/MonographsandPublicAdvisories/Kadcyla/Kadcyla_PM_E.pdf
[2] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm350817.htm
[3] http://www.intmedsafe.net/ArticleFiles/IMSN%20Alert%20trastuzumab%20emtansine%202014%2005%20final.pdf