Infusion-Related Reactions, Hypersensitivity Reactions

- Treatment with KADCYLA has not been studied in patients who had trastu infusion-related reactions (IRR) and/or hypersensitivity reactions; treatmer for these patients. In EMILIA, the overall frequency of IRRs in patients trea
- KADCYLA treatment should be interrupted in patients with severe IRR and of a life-threatening IRR. Patients should be closely monitored for IRR rea

Thrombocytopenia

- In EMILIA, the incidence of ≥ Grade 3 thrombocytopenia was 14.5% in the the comparator group (overall incidence 31.2% and 3.3%, respectively)
- Monitor platelet counts prior to initiation of KADCYLA and prior to each KA modifications as appropriate

Neurotoxicity

- In EMILIA, the incidence of ≥ Grade 3 peripheral neuropathy was 2.2% in the comparator group (overall incidence 21.2% and 13.5%, respectively)
- Monitor for signs or symptoms of neurotoxicity. KADCYLA should be temp experiencing Grade 3 or 4 peripheral neuropathy until resolution to ≤ Grad

HER2 Testing

- Detection of HER2 protein overexpression or gene amplification is necess for KADCYLA. Perform using FDA approved tests by laboratories with der

Extravasation

- In KADCYLA clinical studies, reactions secondary to extravasation have b The infusion site should be closely monitored for possible subcutaneous in Specific treatment for KADCYLA extravasation is unknown

Nursing Mothers

- Discontinue nursing or discontinue KADCYLA taking into consideration the

Adverse Reactions

- The most common ADRs seen with KADCYLA in EMILIA (frequency > 25 musculoskeletal pain, thrombocytopenia, increased transaminases, heada common NCI-CTCAE (version 3) ≥ Grade 3 ADRs (frequency >2%) were t transaminases, anemia, hypokalemia, peripheral neuropathy and fatigue

You are encouraged to report side effects to Genentech and the FDA. You may c 2555. You may contact the FDA by visiting www.fda.gov/medwatch or calling 1-80

Click here for full Prescribing Information for additional important safety inf WARNINGS.

Reference: 1. KADCYLA Prescribing Information. Genentech, Inc. May 2013.

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1 DNA Way
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