

Important Prescribing Information

Dear Healthcare Provider:

This letter is a follow-up to the Important Drug Warning letter, dated May 3, 2000, from Genentech, Inc., informing you of postmarketing reports of serious adverse events associated with the use of HERCEPTIN® (Trastuzumab). These serious adverse events were characterized as hypersensitivity, infusion, or pulmonary reactions.

Accompanying this letter you will find a new package insert for HERCEPTIN. Your attention is directed to the BOXED WARNING, WARNINGS, and ADVERSE REACTIONS sections, where important new information is provided regarding these serious adverse events.

The risk of these adverse events should be considered in the context of the drug's ability to improve outcomes for women with metastatic breast cancer. We ask that you review the information relating to the serious adverse events contained in the revised labeling when making a medical judgment on the care and treatment of your patients. Specifically, appropriate caution should be exercised if you are using HERCEPTIN in patients with significant pre-existing pulmonary compromise.

Experience has shown that when added to chemotherapy, in the treatment of women receiving their first non-hormonal treatment for metastatic disease, HERCEPTIN improved response rates, time to disease progression, time to treatment failure, and one-year survival, when compared to results with chemotherapy alone. HERCEPTIN also effected responses in patients receiving HERCEPTIN alone who had progressed following failure of chemotherapy.

Healthcare professionals should report any serious adverse events suspected to be associated with the use of HERCEPTIN to Genentech at 1-800-626-3553, extension 57541. Alternatively, this information may also be reported to the FDA's MedWatch reporting system by phone (1-800-FDA-1088), facsimile (1-800-FDA-0178), on-line (<https://www.accessdata.fda.gov/scripts/medwatch/>) or mailed, using the MedWatch form FDA 3500, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787.

Sincerely,



Susan D. Hellmann, MD, MPH
Executive Vice President
Chief Medical Officer
Genentech, Inc.