

Herceptin[®] (Trastuzumab): Questions and Answers

Key Points

- Herceptin is a monoclonal antibody that attaches to proteins on some cancer cells and slows or stops the growth of the cells (see Question 1).
- Herceptin is used to treat HER-2 positive breast cancer (see Question 3).
- Some serious side effects, including heart muscle damage and allergic reactions, are associated with Herceptin (see Question 5).
- Herceptin is being studied in clinical trials (research studies) for the treatment of breast cancer and other types of cancer (see Question 6).

1. What is Herceptin? How does it work?

Herceptin (trastuzumab) is a monoclonal antibody. Antibodies are substances the body produces to help fight infection or other foreign particles. Monoclonal antibodies are made in the laboratory, and some are designed to attack specific cancer cells.

Herceptin targets cancer cells that “overexpress,” or make too much of, a protein called HER-2 or *erb* B2, which is found on the surface of some cancer cells. Herceptin attaches to the HER-2 positive cancer cells and slows or stops the growth of the cells. Herceptin is used only to treat breast cancers that are HER-2 positive. HER-2 positive cancers overexpress the HER-2 protein or have amplification (too many copies) of the HER-2 gene.

Approximately 20 to 30 percent of breast cancers overexpress HER-2. These tumors tend to grow faster and are generally more likely to recur (come back) than tumors that do not overproduce HER-2.



2. How are tumors tested for HER-2?

The amount of HER-2 protein in the tumor is measured in the laboratory using a test called immunohistochemical (IHC) analysis. The results of the test are measured on a scale from 0 (negative) to 3+ (strongly positive). Patients with tumors that are 3+ on the IHC test are most likely to benefit from Herceptin therapy; those with tumors that are 0 or 1+ are unlikely to benefit from this treatment. Patients with tumors that are 2+ often have an additional test, called fluorescence in situ hybridization (FISH), to determine whether the tumor is HER-2 positive. FISH measures the number of copies of a gene. Tumors with too many copies of the HER-2 gene as determined by the FISH test are considered positive.

3. How is Herceptin used in the treatment of cancer?

Herceptin is approved by the U.S. Food and Drug Administration (FDA) for the treatment of metastatic breast cancer (breast cancer that has spread to other parts of the body) that is HER-2 positive. The FDA approved Herceptin after two clinical trials (research studies) with women whose metastatic breast cancers produced excess amounts of HER-2 demonstrated that Herceptin was safe and effective.

In 2005, the results of four clinical trials showed that Herceptin is also effective in the treatment of early-stage breast cancer that overexpresses HER-2. In all four studies, women who received Herceptin and chemotherapy lived longer and had significantly less chance of the breast cancer coming back than patients who received chemotherapy alone.

4. How is Herceptin given? What are some of the common side effects of Herceptin?

Herceptin is given by infusion (a method of putting fluids, including drugs, into the bloodstream). The first dose of Herceptin is usually given over a 90-minute period, and the nurse or doctor watches the patient for signs of side effects. If the patient tolerates this dose well, smaller maintenance doses can be given over a 30-minute period.

Side effects that most commonly occur during the first treatment with Herceptin include fever and/or chills. Other possible side effects include pain, weakness, nausea, vomiting, diarrhea, headaches, difficulty breathing, and rashes. These side effects generally become less severe after the first treatment with Herceptin.

Patients who receive Herceptin along with chemotherapy may experience side effects that are different from those of patients who take Herceptin by itself. For example, anemia (a condition in which the number of red blood cells is below normal) and infection, primarily mild upper respiratory infection, have been seen more often in patients given Herceptin with chemotherapy compared with those receiving Herceptin alone. Patients should discuss any concerns about the side effects of treatment with their doctor. The doctor may be able to make suggestions for managing side effects.

5. Can Herceptin cause any serious side effects?

Yes. Herceptin can cause heart muscle damage that can lead to heart failure. Heart failure is a serious condition in which the heart cannot pump enough blood throughout the body. Symptoms of heart failure include shortness of breath, difficulty breathing, and swelling of the feet or lower legs.

Herceptin can also affect the lungs, causing severe or life-threatening breathing problems that require immediate medical attention.

In addition, Herceptin can cause hypersensitivity (allergic) reactions that can be severe or life-threatening. Symptoms of a reaction include a drop in blood pressure, shortness of breath, rashes, and wheezing. Most patients who experience hypersensitivity reactions do so when the drug is being given or within 24 hours after treatment.

Because of these potentially life-threatening side effects, doctors evaluate patients carefully for any heart or lung problems before starting treatment. Doctors and nurses also monitor patients closely during treatment. Patients who develop any problems during or after treatment should call the doctor immediately or go to the nearest emergency care facility.

6. Is Herceptin still being studied in clinical trials?

Yes. Clinical trials are ongoing to test the safety and effectiveness of Herceptin for breast and other types of cancer. People interested in taking part in a clinical trial should talk with their doctor. Information about clinical trials is available from the National Cancer Institute's (NCI) Cancer Information Service (CIS) (see below) at 1-800-4-CANCER and in the NCI booklet *Taking Part in Cancer Treatment Research Studies*, which can be found at <http://www.cancer.gov/publications> on the Internet. This booklet describes how research studies are carried out and explains their possible benefits and risks. More information about clinical trials is available at <http://www.cancer.gov/clinicaltrials> on the NCI's Web site. The Web site offers detailed information about specific ongoing studies by linking to PDQ[®], the NCI's comprehensive cancer information database.

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Related NCI materials and Web pages:

- National Cancer Institute Fact Sheet 7.2, *Biological Therapies for Cancer: Questions and Answers* (<http://www.cancer.gov/cancertopics/factsheet/Therapy/biological>)
- National Cancer Institute Fact Sheet 7.49, *Targeted Cancer Therapies: Questions and Answers* (<http://www.cancer.gov/cancertopics/factsheet/Therapy/targeted>)
- *Taking Part in Cancer Treatment Research Studies* (<http://www.cancer.gov/clinicaltrials/Taking-Part-in-Cancer-Treatment-Research-Studies>)

For more help, contact:

NCI's Cancer Information Service

Telephone (toll-free): 1-800-4-CANCER (1-800-422-6237)

TTY (toll-free): 1-800-332-8615

LiveHelp[®] online chat: <https://cissecure.nci.nih.gov/livehelp/welcome.asp>

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