

# Herceptin patient education checklist

**This checklist includes important information for you to review with your HER2+ breast cancer patients who are new to Herceptin**, either in the adjuvant or metastatic settings. The topics noted are explored in depth in Herceptin patient education materials designed for patient take-home use (see the inside pad cover for a list of these resources). To help ensure that you have covered important issues with your patient, you may wish to **check off topics as you discuss them**. You may also wish to include this sheet in your patient's file as a record of your discussion.

## Adjuvant Indications

Herceptin is indicated for adjuvant treatment of HER2-overexpressing node-positive or node-negative (ER/PR-negative or with one high-risk feature\*) breast cancer:

- As part of a treatment regimen containing doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- With docetaxel and carboplatin
- As a single agent following multi-modality anthracycline-based therapy

\*High-risk features for ER/PR-positive tumors included tumor size >2 cm, histologic and/or nuclear grade 2/3, and age <35 years.

## Metastatic Indications

Herceptin is indicated:

- In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
- As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

## Boxed WARNINGS and Additional Important Safety Information

### Cardiotoxicity and cardiac monitoring

- **Herceptin administration can result in sub-clinical and clinical cardiac failure manifesting as congestive heart failure (CHF) and decreased left ventricular ejection fraction (LVEF)**
  - The incidence and severity of left ventricular cardiac dysfunction was highest in patients who received Herceptin concurrently with anthracycline-containing chemotherapy regimens
  - Discontinue Herceptin treatment in patients receiving adjuvant therapy and strongly consider discontinuation of Herceptin in patients with metastatic breast cancer who develop a clinically significant decrease in left ventricular function
- Patients should undergo monitoring for decreased left ventricular function before Herceptin treatment, and frequently during and after Herceptin treatment
  - More frequent monitoring should be employed if Herceptin is withheld in patients who develop significant left ventricular cardiac dysfunction
- In one adjuvant clinical trial, cardiac ischemia or infarction occurred in the Herceptin-containing regimens

### Infusion reactions, pulmonary toxicity, and neutropenia

- **Serious infusion reactions and pulmonary toxicity have occurred; fatal infusion reactions have been reported**
  - In most cases, symptoms occurred during or within 24 hours of administration of Herceptin
  - Herceptin infusion should be interrupted for patients experiencing dyspnea or clinically significant hypotension
  - Patients should be monitored until signs and symptoms completely resolve
  - Discontinue Herceptin for infusion reactions manifesting as anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome
- Exacerbation of chemotherapy-induced neutropenia has also occurred

### Pregnancy category D

- Herceptin can cause oligohydramnios and fetal harm when administered to a pregnant woman

### Most common adverse events

- The most common adverse reactions associated with Herceptin use were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, and myalgia

## Patient and caregiver resources



Adjuvant patient core brochure



Adjuvant patient starter kit



Adjuvant caregiver support pack



Metastatic patient core brochure

Contact your Genentech clinical specialist for additional patient materials. If you have any questions about Herceptin, reach out to your Genentech clinical specialist, contact the Genentech Medical Communications department (1-800-821-8590), or visit the "Contact Us" section of our website at [www.gene.com/gene/contact/](http://www.gene.com/gene/contact/).

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## Explanation of Herceptin

- Herceptin is a monoclonal antibody, also known as a biologic therapy—it is *not* a chemotherapy.
- It is used to treat a certain type of breast cancer, called HER2-positive breast cancer.

## Dosing, administration, and duration

- Herceptin is given by intravenous (IV) infusion, which means that it comes through a needle that your nurse inserts into a vein.
- Your first infusion includes a slightly larger dose than subsequent infusions, and may last a little bit longer.
  - The first infusion usually takes about 90 minutes, but it may be slowed or stopped if you experience discomfort from side effects.
  - If the first infusion was well tolerated, later infusions can be given over 30-60 minutes.
- Herceptin may be given along with other therapies, such as chemotherapy, hormonal therapy, or radiation therapy, as recommended by your doctor.
- It's important to take Herceptin for the full time recommended by your doctor.
  - **In the adjuvant setting:** Herceptin should be taken for a full year.
  - **In the metastatic setting:** Herceptin should be given until the tumor grows larger or spreads to other areas of the body.

## Side effects

- Call your healthcare provider right away if you experience any of the following: new onset or worsening shortness of breath, cough, swelling of the ankles/legs, swelling of the face, palpitations, weight gain of more than 5 pounds in 24 hours, dizziness, or loss of consciousness.
- Herceptin treatment can result in heart problems, including those without symptoms (reduced heart function) and those with symptoms (congestive heart failure). The risk and seriousness of these heart problems were highest in people who received both Herceptin and a certain type of chemotherapy (anthracycline).**
- Before taking your first dose of Herceptin, your doctor should check to see if you have any health conditions that may increase your chance of having serious heart problems. In addition, you should be frequently monitored for decreasing heart function during the time you are receiving Herceptin and after your last dose of Herceptin.
- Some patients have had serious infusion reactions and lung problems; fatal infusion reactions have been reported. In most cases, these reactions occurred during or within 24 hours of receiving Herceptin.**
- When you receive the first dose of Herceptin, you may have chills and fever as well as nausea, vomiting, pain, headache, dizziness, shortness of breath, low blood pressure, rash, and weakness.
- Herceptin can cause harm to the fetus when taken by a pregnant woman. This may be related to a lowering of amniotic fluid levels in the second and third trimesters. You should use effective contraceptive methods while receiving Herceptin and for at least 6 months after you finish taking Herceptin.
- The most common side effects associated with Herceptin were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, shortness of breath, rash, low white and red blood cells, and muscle pain.
- Because everyone is different, it is not possible to predict what side effects any one person will have. If you have questions or concerns about side effects, talk to your doctor.

## Herceptin insurance support information

- Access Solutions and the Genentech® Access to Care Foundation (GATCF) may help with insurance questions and may assist qualified patients to receive Herceptin.
  - Access Solutions: 1-888-249-4918
  - GATCF: 1-800-530-3083

## Patient and caregiver support and information

- Professional organizations can help patients and their caregivers.

Please see inside pad cover for an abbreviated catalogue of appropriate patient materials.

## Healthcare provider contact information

- Call our office with emergencies or questions at (\_\_\_\_)\_\_\_\_\_.

Please see accompanying full Prescribing Information and inside pad cover for **Boxed WARNINGS** and additional important safety information.

[www.herceptin.com](http://www.herceptin.com)

