Prescribing Information, including Information throughout, and the accompanying full
Please see additional select Important Safety

Be sure to contact your doctor if you:

• Weight loss
• Swelling of the mouth lining
• Diarrhea
• Feeling sick to your stomach (nausea)
• Fever
• Upper respiratory tract infections
• Muscle pain
• Low white and red blood cell counts
• Rash

SEVERE LUNG PROBLEMS
• Fluid in or around the lungs
• Severe shortness of breath

What Should I Ask My Doctor?

What is my HER2-positive breast cancer hormone receptor–positive or progesterone receptor (ER/PR)-negative or have one high-risk feature.

How is my Herceptin treatment different from traditional chemotherapy?

About Treatment

What are my treatment options?

What are the most common side effects seen with HERCEPTIN?

• Hair loss
• Nausea
• Diarrhea
• Feeling sick to your stomach
• Swelling of the mucous membranes

What if I miss a dose of HERCEPTIN?

About HERCEPTIN

Herceptin is approved for the treatment of early-stage breast cancer that is HER2-positive (HER2+) and has spread into the lymph nodes, or is HER2-positive and has not spread into the lymph nodes. If it has not spread into the lymph nodes, the cancer needs to be estrogen receptor/progesterone receptor (ER/PR)-negative or have one high-risk feature.

High risk is defined as ER/PR-positive with one of the following features: tumor size >2 cm, age <35 years, or tumor grade 2 or 3.

The HER2 protein is an abnormal receptor that helps control how a cell grows and divides. When it is overproduced in the breast, it causes the cells to grow and divide abnormally, similar to a tumor. The HER2 protein can be measured in tissues from tumors and in the blood serum of women with breast cancer.

About Side Effects

Side Effects Seen Most Often With HERCEPTIN

• Hair loss
• Nausea
• Diarrhea
• Feeling sick to your stomach
• Swelling of the mucous membranes
• Fever
• Upper respiratory tract infections
• Muscle pain
• Low white and red blood cell counts
• Rash
• Feeling tired

INFUSION REACTIONS, including:

• Anaphylaxis
• Hypersensitivity reactions

About Heart Failure

HEART PROBLEMS

• These signs usually happen within 24 hours after receiving HERCEPTIN.

About the MotHER Pregnancy Registry

Encouraged to enroll in the MotHER Pregnancy Registry by contacting 1-800-690-6720

Boxed WARNINGS.

HERCEPTIN is not for everyone. Be sure to contact your doctor if you are experiencing any of these side effects:

• Anaphylaxis
• Hypersensitivity reactions

HERCEPTIN contains trastuzumab, which is a humanized monoclonal antibody. It is a protein and when used as a medicine, it may cause an allergic reaction.

Although some people may have a life-threatening side effect, most do not.
Important Patient Safety Information (continued)

Possible Serious Side Effects With HERCEPTIN

Be sure to contact your doctor if you:

- Have any signs of SEVERE LUNG PROBLEMS, including:
  - Severe shortness of breath
  - Fluid in or around the lungs
  - Weakness of the diaphragm
  - Not enough oxygen in the body
  - Swelling of the lungs
  - Scarring of the lungs

Your doctor may check for signs of severe lung problems when he or she examines you.

LOW WHITE BLOOD CELL COUNTS

Low white blood cell counts can be life threatening. Low white blood cell counts were seen more often in patients receiving HERCEPTIN plus chemotherapy than in patients receiving chemotherapy alone.

Your doctor may check for signs of low white blood cell counts when he or she examines you.

Other Important Information

Before taking HERCEPTIN, you must have a HER2 test to determine if your cancer is HER2-positive. This is because the benefit of treatment with HERCEPTIN has been shown only in patients whose tumors are HER2-positive.

Side Effects Seen Most Often With HERCEPTIN

Some patients receiving HERCEPTIN for breast cancer had the following side effects:

- Fever
- Feeling sick in your stomach (nausea)
- Throwing up (vomiting)
- Infection
- Diarrhea
- Vomiting
- Increased cough

Some patients receiving HERCEPTIN for metastatic stomach cancer had the following side effects:

- Low white blood cell counts
- Diarrhea
- Feeling tired
- Low red blood cell counts
- Swelling of the mouth
- Weight loss

Some patients receiving HERCEPTIN for metastatic breast cancer had the following side effects:

- Upper respiratory tract infections
- Fever
- Rash
- Low platelet counts
- Swelling of the mucous membranes
- Swelling of the nose and throat

You should contact your doctor immediately if you have any of the side effects listed above.

You are encouraged to report side effects to Genentech and the FDA. You may report side effects to the FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-635-2055.

Please see additional select Important Safety Information throughout, and the accompanying full Prescribing Information, including Boxed WARNINGS.
What should I do to be ready for my infusion (cancer treatment given intravenously)?

How often will my heart be tested?

How often will my nurse follow up with my oncologist (a doctor who treats patients with cancer) about my Herceptin treatment and my progress?

Are there any symptoms or problems I might have during my Herceptin treatment that I should immediately tell you about?

How often will my heart be tested?

What is HERCEPTIN For?

Herceptin is approved for the treatment of early-stage breast cancer that is HER2 positive and has spread into the lymph nodes, or is HER2 positive and has not spread into the lymph nodes. It has not spread into the lymph nodes, the cancer needs to be estrogen receptor/ progesterone receptor (ER/PR) negative or have one or more high-risk features. Herceptin can be used in several different ways:

• As part of a treatment course including the chemotherapy drugs doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel. This treatment course is known as "AC-TH.

• With the chemotherapy drugs docetaxel and carboplatin. This treatment course is known as "TCH.

• Alone after treatment with multiple other therapies, including an anthracycline (doxorubicin-like) drug and a type of chemotherapeutic agent known as "HERCEPTIN." These include heart problems—such as congestive heart failure or reduced heart function—with or without symptoms. The rate of and seriousness of these heart problems were highest in people who received both HERCEPTIN and a certain type of chemotherapy (anthracycline). In a study of adjuvant (early) breast cancer, one patient died of significantly weakened heart muscle.

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Possible Serious Side Effects With HERCEPTIN

Not all people have serious side effects, but side effects with HERCEPTIN therapy are common. Although some people may have a life-threatening side effect, most do not. Your doctor will stop treatment if any serious side effects occur. HERCEPTIN is not for everyone. Be sure to contact your doctor if you are experiencing any of the following.

HEART PROBLEMS

These include heart problems—such as congestive heart failure or reduced heart function—with or without symptoms. The rate of and seriousness of these heart problems were highest in people who received both HERCEPTIN and a certain type of chemotherapy (anthracycline). In a study of adjuvant (early) breast cancer, one patient died of significantly weakened heart muscle. Your doctor will check for signs of heart problems before, during, and after treatment with HERCEPTIN.

INFUSION REACTIONS, including:

• Fever and chills
• Feeling sick to your stomach (nausea)
• Shivering (not being cold)
• Rash (n some cases at tumor sites)

These signs usually happen within 24 hours after receiving HERCEPTIN.

Be sure to contact your doctor if you:

• Are a woman who could become pregnant, or may be pregnant Treatment with HERCEPTIN may result in the death of an unborn baby and birth defects. Birth control should be used while receiving HERCEPTIN and after your last dose of HERCEPTIN. If you are a woman who could become pregnant, or may be pregnant, you are encouraged to enroll in the Multinational Pregnancy Registry (by contacting 1-800-639-0202 or visiting http://www.motherpregnancyregistry.com) and to report HERCEPTIN exposure to Genentech at 1-888-835-2555.

(Important Safety Information continues on following page)

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