



INFORMATION ABOUT

Trastuzumab (Herceptin®) for patients with early breast cancer

This information has been developed to help you understand and make decisions about the use of trastuzumab (Herceptin®) for the treatment of early breast cancer. The information has been developed by a multidisciplinary working group and is based on the National Breast Cancer Centre guideline *Recommendations for use of trastuzumab (Herceptin®) for the treatment of HER2-positive breast cancer*.

To view or download a copy of the guideline go to www.nbcc.org.au/resources

This information supplements the National Breast Cancer Centre's *A Guide for Women with Early Breast Cancer 2003*. Information about trastuzumab for patients with metastatic breast cancer can be found on the National Breast Cancer Centre's website www.nbcc.org.au.

WHAT IS EARLY BREAST CANCER?

WHAT IS TRASTUZUMAB (HERCEPTIN®)?

How do I know if I am HER2-positive?

Why take trastuzumab?

When should I start treatment with trastuzumab?

How is trastuzumab given?

SIDE EFFECTS OF TRASTUZUMAB

Other side effects of trastuzumab

DECIDING WHETHER TO TAKE TRASTUZUMAB

Who should I talk to about trastuzumab?

Questions to ask your doctor about trastuzumab

Questions yet to be answered about trastuzumab

Information about the Pharmaceutical Benefits Scheme (PBS) listing

FREQUENTLY ASKED QUESTIONS

GLOSSARY

WHAT IS EARLY BREAST CANCER?

Early breast cancer is cancer that is contained in the breast and may or may not have spread to the lymph nodes in the breast or armpit. Some cancer cells may have spread outside the breast and armpit area, but cannot be detected.

WHAT IS TRASTUZUMAB (HERCEPTIN®)?

Trastuzumab is a drug used to treat a type of breast cancer called 'HER2-positive breast cancer'. 'HER2-positive' means that the breast cancer cells have higher than normal levels of a protein – called the HER2 protein – on their surface. Trastuzumab is an antibody that works by attaching itself to HER2-positive cancer cells and stopping the cells from growing and dividing.

HOW DO I KNOW IF I AM HER2-POSITIVE?

About one in five patients diagnosed with breast cancer have HER2-positive breast cancer. Your pathology report shows whether your breast cancer cells are HER2-positive. There are two ways for a pathologist to test for HER2:

- IHC (immunohistochemistry) is a test that measures the amount of HER2 protein on the cells
- ISH (in-situ hybridisation) is a test that measures the amount of the HER2 gene in the cells; there are two types of ISH tests.

All breast cancer cells have some HER2 protein, but only an IHC score of 2+ (with subsequent confirmation by ISH test), IHC score of 3+ or a positive ISH result shows that the breast cancer cells are HER2-positive. Talk to your doctor about whether your cancer is HER2-positive. You can also ask your doctor for a copy of your pathology report.

If your breast cancer cells are not HER2-positive, trastuzumab will have no benefit for you.

WHY TAKE TRASTUZUMAB?

Clinical trials have shown that trastuzumab lowers the risk of breast cancer coming back (in the breast and in other parts of the body) and increases survival for women with HER2-positive early breast cancer.

What did the trials show

In clinical trials, women with early breast cancer who received trastuzumab and chemotherapy reduced their absolute risk of breast cancer coming back by between 5% and 13% and reduced their absolute risk of death by between 1% and 7%. The period of follow-up in these clinical trials was short (1–3 years) and the benefits reported may increase or decrease with longer follow-up.

WHEN SHOULD I START TREATMENT WITH TRASTUZUMAB?

The current recommendation for people with early breast cancer is to give trastuzumab at the same time as chemotherapy (usually after breast cancer surgery). Trastuzumab can only be given with some types of chemotherapy and therefore treatment with trastuzumab may not start immediately at the beginning of chemotherapy. Trastuzumab can be given at the same time as radiotherapy. However, the long-term effects of giving trastuzumab at the same time as radiotherapy are not known.

If your breast cancer is large, you may receive chemotherapy before breast cancer surgery, to shrink the breast cancer and make it easier to remove by surgery. In this situation, your doctor may recommend that you start trastuzumab together with more chemotherapy after surgery.

HOW IS TRASTUZUMAB GIVEN?

Trastuzumab is given by slow intravenous (IV) infusion (a method of putting fluids, including drugs, into the bloodstream). A health care professional gives the infusion once a week or once every 3 weeks. You and your doctor will decide how frequently trastuzumab is given. The dose will depend on your body weight. The first time you receive trastuzumab, you will be given a higher dose called a 'loading dose'. This will usually take about 90 minutes and can be slowed or stopped if you feel any discomfort. If you have no reaction to the first infusion, the other infusions will be quicker and the dose will be lower.

HOW LONG WILL I BE TREATED WITH TRASTUZUMAB FOR?

The current recommendation is to give trastuzumab for 1 year. Clinical trials are examining whether trastuzumab is more effective if given for 2 years and whether trastuzumab is as effective if given for a shorter period.

SIDE EFFECTS OF TRASTUZUMAB

The most significant side effect of trastuzumab is the risk of heart problems. The risk of heart problems can be increased if trastuzumab is taken with certain types of chemotherapy, known as anthracyclines. Ask your doctor about the possible side effects of trastuzumab. Your doctor will explain whether your chemotherapy will change if you receive trastuzumab.

Trastuzumab is not recommended for patients with pre-existing heart problems. Before starting trastuzumab treatment your doctor will check your heart using an echocardiogram or a multi-gated acquisition (MUGA) scan. Your doctor should also check your heart at intervals while you are receiving treatment. Patients who develop heart problems whilst receiving trastuzumab should be checked more frequently and may need to be referred to a cardiologist.

Some of the symptoms of heart problems may include very low blood pressure, difficulty breathing, tightness in the chest, chest pains, shortness of breath or an irregular heartbeat.

Trastuzumab is not recommended for people who have a history of heart problems and should not be given to patients who are receiving anthracycline chemotherapy (epirubicin, doxorubicin, adriamycin).

OTHER SIDE EFFECTS OF TRASTUZUMAB

Other possible side effects of trastuzumab include allergic reactions, such as chills and fever. Trials that have examined the effects of trastuzumab in women with early breast cancer have not been running for many years. Therefore, longer term side effects of trastuzumab are not yet known. Let your doctor know about any new symptoms or if any of your symptoms become worse.

DECIDING WHETHER TO TAKE TRASTUZUMAB

Deciding whether trastuzumab therapy is right for you will depend on many things. You and your doctor will need to consider the absolute benefits and harms with and without trastuzumab therapy, your general health, and your preference for treatment.

WHO SHOULD I TALK TO ABOUT TRASTUZUMAB?

Your treating specialist will consider the most appropriate treatment options for you and will discuss whether trastuzumab is recommended in your case. If you have any questions you should ask your oncologist or breast care nurse. You may also wish to speak with other women who are taking trastuzumab. It is important that you talk to your treating doctor or specialist about possible side effects of treatment and ways of managing these side effects if they develop.

QUESTIONS TO ASK YOUR DOCTOR ABOUT TRASTUZUMAB

- Can I benefit from treatment with trastuzumab?
- What are my other treatment options if trastuzumab is not of benefit to me?
- How much will trastuzumab cost?
- When will I start trastuzumab if I am having other treatments?
- How will trastuzumab be given?
- Will I need to go to hospital to receive trastuzumab?
- How often will I need to receive treatment?
- Are there any extra tests or follow-up that is needed?
- How much will any extra tests cost?
- What are the possible side effects of trastuzumab?
- When are side effects likely to occur?
- Who should I contact if side effects happen?
- How can I manage side effects if they develop?
- Will the side effects stop or improve when I finish treatment?
- Can I participate in any clinical trials?

QUESTIONS YET TO BE ANSWERED ABOUT TRASTUZUMAB

As with many drugs for breast cancer, there are important things that we still don't know about trastuzumab. Clinical trials to answer these questions are ongoing and more information will become available in the future. Some of these questions include:

- the long-term effects of trastuzumab, including effects on the heart and brain
- the ideal length of time for which trastuzumab should be taken

continued overleaf

- the ideal combination of trastuzumab with other therapies like chemotherapy, hormonal therapy and radiotherapy
- the effects of taking trastuzumab at the same time as endocrine therapies
- the use of trastuzumab in pregnancy, and impact on fertility and contraception.

INFORMATION ABOUT THE PHARMACEUTICAL BENEFITS SCHEME (PBS) LISTING FOR HERCEPTIN® (TRASTUZUMAB) as of July 2007

For updates after July 2007 go to <http://www.medicareaustralia.gov.au/providers> then type in Herceptin as a search term.

Herceptin® (trastuzumab) is currently subsidised for the treatment of HER2-positive patients with early breast cancer concurrently with chemotherapy following surgery. Restrictions apply; visit the Medicare website for further information.

FREQUENTLY ASKED QUESTIONS

Question: How do I know if trastuzumab will be of benefit to me?

Answer: Trastuzumab will only be of benefit to you if your breast cancer cells are HER2-positive. About one in five patients diagnosed with breast cancer have HER2-positive breast cancer. Ask your doctor whether your cancer is HER2-positive.

Question: How often will I need to receive treatment?

Answer: Trastuzumab can be given weekly or 3-weekly. Your doctor will decide the best dosage and treatment regimen for you.

Question: What happens if I have to stop trastuzumab before 1 year of treatment for any reason?

Answer: One small clinical trial suggested that treatment with 9 weeks of trastuzumab may be enough to give benefit to some women with early breast cancer.

Question: Will I lose my hair whilst receiving trastuzumab?

Answer: No, hair loss is not a common side effect of trastuzumab. If you are receiving trastuzumab in combination with chemotherapy, you may experience hair loss due to the chemotherapy.

GLOSSARY

Absolute risk: A person's chance of developing a disease over a specific time period.

Cardiologist: A doctor who specialises in heart problems.

Echocardiogram: A type of ultrasound test that looks at the size, shape and function of the heart.

Median: One type of average, found by arranging the values in order and then selecting the one in the middle.

Multi-gated acquisition (MUGA) scan: A test that measures how well the heart pumps blood.

Relative risk: A comparison of the risk of developing a disease in two different population groups.

Membership of the NBCC Herceptin® Consumer Information Subgroup

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