



INFORMATION ABOUT

Trastuzumab (Herceptin®) for patients with metastatic breast cancer

This information has been developed to help you understand and make decisions about the use of trastuzumab (Herceptin®) for the treatment of metastatic 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 replaces *Chapter 8: New Anti-cancer Treatments* in the National Breast Cancer Centre's *A Guide for Women with Metastatic Breast Cancer 2001*. Information about trastuzumab for patients with early breast cancer can be found on the National Breast and Ovarian Cancer Centre's website www.nbcc.org.au.

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WHAT IS METASTATIC BREAST CANCER?

Metastatic breast cancer is the term used to describe cancer that has spread from the original site in the breast (+/- regional nodes) to other organs or tissues in the body. It may also be called advanced or secondary breast cancer.

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 can decrease the size of secondary breast cancers and can increase survival for patients with HER2-positive metastatic breast cancer.

What did the trials show?

Women with metastatic breast cancer treated with trastuzumab and chemotherapy lived longer than women treatment with chemotherapy alone. One trial found a median survival increase of 5 months; another reported a median survival increase of 8.5 months for women treated with trastuzumab and chemotherapy compared with women treated with chemotherapy alone.

WHEN SHOULD I START TREATMENT WITH TRASTUZUMAB?

The current recommendation for patients who have not already received chemotherapy for metastatic breast cancer is to give trastuzumab at the same time as chemotherapy. Trastuzumab can also be given alone to patients who have already received chemotherapy for metastatic disease or if chemotherapy is not appropriate.

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.

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?

Treatment with trastuzumab will usually continue as long as you are benefiting from treatment, and as long as the benefits outweigh the risks and side effects. Talk to your oncologist about the expected length of treatment for you.

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. If trastuzumab is given with certain types of chemotherapy side effects can include anaemia (a decrease in the number of red blood cells), leukopenia and neutropenia (a decrease in the number of white blood cells). These effects on the blood cells are due to the chemotherapy and not trastuzumab. Central nervous system (brain) metastases may occur more frequently in women receiving trastuzumab. Let your doctor know of any new symptoms or changes in the severity of your symptoms.

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 receive treatment?
- Will I need any extra tests or follow-up if I am receiving trastuzumab?
- 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 stop 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 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 metastatic breast cancer:

- in combination with taxanes for patients who have not received chemotherapy for metastatic disease
- as monotherapy for the treatment of those patients who have received one or more chemotherapy regimen(s) for metastatic disease.

FREQUENTLY ASKED QUESTIONS

Questions: 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 once a week or once every 3 weeks. You and your doctor will decide what dosage and frequency is best for you.

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.

Question: How long will trastuzumab be of benefit to me?

Answer: There is no easy answer to this question. It depends on you as an individual. Some women use trastuzumab for many years, for others it only works for a few months. It is usually given until your disease progresses.

- Question:** Is there any need to stop taking trastuzumab if it appears to be working well?
- Answer:** Unless there is something else happening to your breast cancer, it is not necessary to stop taking trastuzumab if it is working well for you.

GLOSSARY

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.

Membership of the NBCC Herceptin® Consumer Information Subgroup

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ISBN Print: 978-1-74127-058-7 Online: 978-1-74127-059-4 CIP: 614.5999449

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