Your guide to Herceptin® (trastuzumab) for HER2+ early breast cancer

For more information on anything covered in this brochure talk to your specialist, doctor or nurse, or visit www.cancerinfo.co.nz
Get wise - knowledge is power.

It’s important to know all the facts before you make any decisions, so we’ve put together this booklet to provide answers to the most commonly asked questions from patients like you, who have been prescribed Herceptin (trastuzumab) for the treatment of HER2-positive (HER2+) early breast cancer.

This booklet has been created as a helpful source of information to support you throughout your treatment, covering topics such as:

- How Herceptin helps
- What you can expect
- Length of time you will need to take Herceptin
- Where you can find help when you need it

This booklet is not a substitute for any professional guidance, advice or help provided by your doctor, nurse or pharmacist.

Be positive

Your most important asset right now is a positive attitude. With a strong mind, faith in yourself, treatments available, and the help of your whanau and friends, you can fight your breast cancer.

More information can be obtained from the websites listed on the back page of this booklet.

If you have other questions or concerns about your treatment with Herceptin, please contact your doctor or nurse.
ABOUT HER2+ BREAST CANCER

What is cancer exactly?
Cancer occurs when cells start growing out of control. Cancer cells can multiply much faster than normal cells and spread to other parts of the body.

In early breast cancer, the uncontrolled cell growth is occurring in the area of the breast and/or armpit. Nowhere else in the body is affected. Early breast cancer is often written as eBC.

What is locally advanced breast cancer?
Locally advanced breast cancer is when cancer cells are confined to the breast and armpit area but the skin or chest wall of the breast are also involved.

The stages of early breast cancer
Knowing the stage of your cancer can help you and your doctor work out the best course of treatment.

- **Stage 0**
  - Cancer has not spread beyond where it started

- **Stage I**
  - Cancer cells are breaking through to normal breast tissue

- **Stage II**
  - Tumour is between 20-50mm in size and/or - cancer has spread to lymph nodes under the arm

- **Stage IIIA**
  - Tumour is more than 50mm and/or affects lymph nodes under the arm
WHAT IS HER2?

HER2 is a protein on the surface of all normal cells in your body. HER2 helps regulate the way cells grow and divide into other cells.

So what is HER2+ breast cancer?

When too much HER2 is present or expressed on the outside of some of your cells, these cells become ‘abnormal’. The abnormal cells start multiplying rapidly and producing more abnormal cells. This group of abnormal cells is termed a tumour.

How do you know if you’re HER2+?

There are a number of different tests to determine each kind of cancer.

One of these is HER2 and is critical in identifying the most appropriate treatment for you.

Your specialist will have sent a sample of your breast cancer cells to a laboratory for a HER2 test.

Combined with other test results your HER2 status allows your oncologist to decide which treatment[s] will be the best at fighting your cancer.

You can also find out more about these tests via one of the websites listed on the Resources page 21.

About 1 in 5 women diagnosed with breast cancer in New Zealand are HER2+.

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About 1 in 5 women diagnosed with breast cancer in New Zealand are HER2+.

HER2 means Human Epidermal Growth Factor Receptor Type 2

HER2+ means the same as HER2-positive

HER2- means the same as HER2-negative

All women with newly–diagnosed breast cancer or a new breast cancer recurrence should be routinely tested for HER2.
ABOUT HERCEPTIN

What is Herceptin?

Herceptin is an anticancer therapy for women with HER2+ breast cancer.
The active ingredient in Herceptin is trastuzumab (traz-too-za-mab), a biological treatment known as a monoclonal antibody.

What is a monoclonal antibody?

A monoclonal antibody is a type of biological therapy that uses the body’s natural immune defences.

Unlike conventional treatments such as surgery, radiotherapy and chemotherapy, Herceptin only targets and kills cancer cells that overexpress the HER2 protein.

So what does Herceptin do exactly?

Herceptin helps slow or stop the growth of HER2+ cells after you’ve had surgery and chemotherapy. These cells can turn into new tumours if left untreated.

How is Herceptin given?

Herceptin treatment is given as an intravenous (IV) infusion (drip) or a subcutaneous (SC) injection (beneath the skin). Treatment usually begins after surgery and either during or after chemotherapy.

* Herceptin IV infusion is fully funded. Herceptin SC is currently not funded which means that patients need to pay for this medicine themselves.

How does Herceptin work?

Unlike conventional treatments such as surgery, radiotherapy and chemotherapy, Herceptin only targets and kills cancer cells that over-express the HER2 protein. Herceptin works via four different ways:

1. Activating the body’s own immune system... to kill HER2 cancer cells
2. Blocking HER2 activated cell growth... by binding to HER2 proteins
3. Preventing the formation of a very active form of the HER2 protein
4. Stopping the formation of new blood vessels at the site of the primary tumour

How effective is Herceptin?

Every woman’s risk of cancer returning is different. Herceptin is one treatment that can help reduce this risk for women with HER2+ breast cancer. How Herceptin will benefit you depends on your individual circumstance. Discuss this with your oncologist.

How long should I take Herceptin for?

Three large international studies have shown that 1 year of Herceptin treatment, when combined with chemotherapy, improved the chances of living free of breast cancer even 10 years later.

The use of 1 year of Herceptin IV is widely accepted and is funded by the Ministry of Health for 12 months in eBC.*

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HERCEPTIN® (trastuzumab)

Three things to remember

1. Herceptin targets HER2+ proteins on breast cancer cells to help your body’s immune system fight the cancer
2. Herceptin is given during or after chemotherapy and increases your chances of survival by helping prevent HER2+ cells growing back
3. When used for 1 year Herceptin offers HER2+ eBC patients the best chance of improved survival

Herceptin can also enhance the effectiveness of chemotherapy, which attacks and damages the DNA in cancer cells causing the cells to die.
ABOUT YOUR TREATMENT

How is Herceptin given to you?
Herceptin may be given as an IV infusion or by a subcutaneous (SC) injection in the thigh. This usually takes place in the cancer department at a hospital or clinic. You may receive Herceptin by itself or in combination with other breast cancer treatments. Your specialist will decide which combination of treatments is best for you.

Can you drive after receiving Herceptin?
Herceptin does not generally cause any problems with your ability to drive or operate machinery. However, Herceptin can cause side effects such as chills and lightheadedness, particularly after the first dose. It’s important not to drive until these symptoms have cleared or until you know how Herceptin affects you. It’s a good idea to bring a friend or family member to drive you home the first time you have Herceptin.

How long will the infusion take?
The first infusion of Herceptin will generally be given over 90 minutes. After the infusion you will need to wait for a short time to make sure you don’t have a reaction to the Herceptin. If the initial infusion was well tolerated, the subsequent doses will generally last 30 minutes. The infusion may take longer if it is slowed or interrupted, if you experience side effects or have an allergic reaction.

How long does the SC injection take?
Herceptin SC is given as an injection under the skin in the thigh over two to five minutes. Doses are given every three weeks.
BEFORE STARTING HERCEPTIN

Tell your specialist if:

- you have a history of:
  - coronary artery disease
  - high blood pressure
  - heart failure
  - abnormal beating of the heart
  - angina (chest pain)
- you have previously been treated with chemotherapy medicines known as anthracyclines (e.g. doxorubicin)
- if you have any breathing or lung problems
- you are pregnant or plan to become pregnant
- you are breast-feeding or plan to breast-feed
- you are allergic to any other medicines or any other substances such as foods, preservatives or dyes
- you are taking any other medicines, including vitamins or herbal remedies you’ve bought from a pharmacy, supermarket or health food shop

Important: It is never too late to tell your doctor about any of the above, even if you are already on Herceptin
DURING THE COURSE OF YOUR HERCEPTIN THERAPY

Important information

• tell all doctors, dentists, pharmacists and other healthcare professionals treating you that you are receiving Herceptin

• tell your specialist or healthcare professional if you have any chest pain, difficulty breathing, shortness of breath and/or swelling of your feet and hands while you’re receiving Herceptin

• tell your specialist if you become pregnant while receiving Herceptin

• tell your specialist if you feel Herceptin is not helping your condition

• do not take any other medicines [whether prescription or not] without telling your specialist or consulting a pharmacist first

• be careful driving or operating machinery until you know how Herceptin affects you

Will you need medical tests during treatment?

Yes. Your heart function will be regularly monitored during Herceptin therapy. Every three months or so you’ll have an echocardiogram (ultrasound heart scan) or a MUGA (Multiple Gated Acquisition heart scan) so your specialist can check your heart function.

Your specialist may pause or stop your Herceptin treatment if your heart function is being affected. Herceptin treatment can be restarted in some circumstances if your specialist considers it safe to do so.

You may also need to have blood tests, X-rays and CT or MRI scans to help your specialist check for side effects and monitor your body’s reaction to Herceptin therapy.

Please keep all of your specialist appointments so your progress can be checked.
SIDE EFFECTS:

Herceptin helps most people with HER2+ breast cancer but it may have some unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Because Herceptin may be used with other medicines that treat breast cancer, it may be difficult for your doctor to tell whether the side effects are due to Herceptin or due to the other medicines.

For a full list of Herceptin side effects, please see the Herceptin Consumer Medicines Information, available from www.medsafe.govt.nz/consumers/cmi/h/herceptin.pdf

Will your hair fall out?

Herceptin is generally well tolerated and does not have the same side effects as chemotherapy, such as hair loss, severe nausea and vomiting and increased risk of infection. However, if you receive Herceptin AND chemotherapy you may also experience the side effects of the chemotherapy medicine you are being treated with. See the Herceptin Consumer Medicines Information for a list of side effects you may experience.

Safety

Three things to remember

1. If you experience any side effects, tell your specialist or health care professional immediately
2. Your Herceptin treatment may be stopped until your side effects resolve
3. Treatment is usually re-started and may include medication to help treat your symptoms
DURING AND AFTER TREATMENT

If you’re recovering from breast cancer treatment, your main focus is on getting well.

Anything you can do to reduce your stress and to enhance your comfort, joy, and satisfaction can have a major effect on your wellbeing. Meditation, yoga, visualisation exercises, and prayer may be valuable additions to your daily or weekly routine.

Healthy eating means eating a variety of foods that give you the nutrients you need to maintain your health, feel good, and have energy. These nutrients include protein, carbohydrates, fat, water, vitamins, and minerals.

Try to choose the most nutritionally rich foods you can from each food group each day—those packed with vitamins, minerals, fibre, and other nutrients, but also lower in calories. Pick foods like fruits, vegetables, whole grains, and fat-free or low fat milk and milk products.

Regular exercise

You can be physically active in many ways. These opportunities may be structured or unstructured, planned or unplanned, and take place in a variety of settings.

Just 30 minutes of moderate physical activity on most days of the week will improve health and wellbeing.

Activities might be brisk walking, dancing, or lawn mowing. Check with your doctor to see what they recommend.

Maintain a healthy weight

Evidence shows that carrying too much body fat increases your risk of developing some cancers.

Likewise, the evidence shows that people who have maintained a healthy body weight and remained physically active throughout life are most likely to have a reduced risk of cancer.

What can you do to help yourself?

Three things to remember

1. Healthy eating
2. Regular exercise
3. Take time to relax
RESOURCES

Organisations

The following groups know what you are going through and can offer you support and valuable information.

Cancer Society of NZ
W: www.cancernz.org.nz
Ph: 0800 226 237

NZ Breast Cancer Foundation
W: www.nzbcf.org.nz
Ph: (09) 304 0766
TF: 0800 902 732
PO: PO Box 99 650, Newmarket, Auckland

For more information on HER2+ breast cancer and Herceptin visit www.cancerinfo.co.nz

Important numbers

Specialist: ___________________________ Nurse: ___________________________
Phone: ______________________________ Phone: ___________________________

Clinic: ______________________________ Pharmacist: _______________________
Phone: ______________________________ Phone: ___________________________

Nurse: ______________________________ 24 Hour contact: _____________________
Phone: ______________________________ Phone: ___________________________
Glossary of Terms

**Active Ingredient** - drug being tested in clinical trial.

**Adjuvant therapy** - treatment given to reduce the chance of a cancer coming back. It comes after the main treatment plan (usually surgery) and may include chemotherapy, radiation therapy, hormone therapy, and biological treatments such as Herceptin.

**Antibodies** - a substance produced when antigen is present. The antibodies attach themselves to antigens so cells of the immune system can remove the antigen from the body.

**Antigen** - a substance that stimulates antibodies to be produced.

**Benign** - not malignant, a non-cancerous growth.

**Biopsy** - a tissue sample taken from the body and examined. A biopsy of cancer tissue is taken to help understand what kind of cancer you have and the stage the cancer is at.

**Cancer** - any type of malignant growth or tumour caused by the abnormal and uncontrolled division of cells in the body.

**Carcinoma** - a particular kind of cancerous tumour.

**Chemotherapy** - treatment with medicines that attack and kill rapidly growing cells, including normal cells.

**Clinical trial** - a medical study that tests how safe and effective a medicine or other treatment is.

**Control treatment** - existing treatment that is being compared with the experimental treatment. The control is generally the standard treatment available.

**DCIS: Ductal Carcinoma In Situ** - a non invasive type of breast cancer that is confined to the ducts of the breast. The cancer has not spread to the surrounding breast tissue.

**Ductal carcinoma** - a common type of breast cancer that is invasive. The cancer is not confined to the ducts surrounding breast tissue is affected.

**Ducts** - tubes through which body fluids pass.

**Early breast cancer** - cancer has not spread outside the breast tissue or the lymph nodes in the armpit.

**Ethics committee** - committee that reviews the plan for a clinical trial to ensure it is being conducted ethically.

**Gland** - a group of cells that make and release chemicals, such as hormones, that are then used by other cells in the body.

**HER2** - a protein found on all cells that helps cells grow and divide. It stands for Human Epidermal Growth Factor Receptor Type 2.

**HER2 gene amplification** - when breast cells have more than 2 copies of the HER2 gene.

**Hormone** - protein over-expression - when a lot more HER2 protein than normal is produced and expressed on the cells surface.

**Hormones** - substances produced by organs or cells in your body that affect bodily processes. An example is oestrogen.

**Hormonal therapy** - in breast cancer this is using medicines to block the effects of the hormone oestrogen. Hormone therapy is used to help treat some forms of breast cancer.

**Immunotherapy** - a kind of treatment that stimulates your body’s immune system to help fight the disease.

**Lobules** - small lobes, which are sections of the breast. In the breast, lobules produce milk.

**Lymph** - clear fluid that contains white blood cells and travels through the lymph system.

**Lymph nodes** - pea-sized collections of tissue near the breast under the arm, above the collarbone, and in the chest. They are also found in many other parts of the body.

**Lymphatic system** - tissues and organs that produce and carry lymph fluid from tissues to the circulatory system. The lymphatic system is a major component of the immune system.

**Malignant** - a cancerous or potentially dangerous growth.

**Mastectomy** - surgical removal of the entire breast, most of the lymph nodes under the arm, and sometimes the lining over the chest muscles.

**Metastasis** - the spreading of cancer cells from one part of the body to another.

**Metastatic** - when cancer cells have spread to other parts of the body.

**Monoclonal antibody** - an antibody produced outside the body and is designed to target specific antigens. A target could be the HER2 protein on the surface of some breast cancer cells.

**Neoplasm** - another term for tumours which refers to new and abnormal tissue growth.

**Node-negative** - cancer is not present in the lymph nodes.

**Node-positive** - cancer is present in the lymph nodes.

**Oestrogen** - one of the female hormones that can stimulate some breast cancer tumours to grow.

**Protocol** - an action plan that describes what will be done in a clinical study and why.

**Radiotherapy or Radiation therapy** - cancer treatment that uses x-rays, gamma rays, and alpha and beta particles to destroy cancer cells. Radiotherapy is localised to the tumour area.

**Receptor** - a specific molecule of a cell that recognises and binds with other specific molecules, such as hormones.

**Recurrence** - when cancer returns to the location of the original tumour or another part of the body.

**Standard treatment** - the best treatment known based on results of past research.

**Subcutaneous injection** - an injection given under the skin.

**Tumour** - a mass of tissue formed by the uncontrolled growth of new cells. Tumours can be cancerous (malignant) or non-cancerous (benign).

**White blood cells** - cells of the immune system that help defend the body against foreign particles such as bacteria and viruses.
CONSUMER MEDICINE INFORMATION

Herceptin IV Consumer information

*Herceptin®* (trastuzumab), 150mg and 440mg vials, is a Prescription Medicine used to treat patients with early breast cancer and metastatic (spreading) breast cancer who have tumours with a large amount of the HER2 protein.

**Do not use Herceptin if:** you have early breast cancer and have had an LVEF test (measures how well your heart can pump blood) of less than 45% or you have symptoms of heart failure; you have had an allergic reaction to trastuzumab or any of the ingredients, benzyl alcohol, or to any medicines that are made using Chinese hamster ovary cells.

**Tell your doctor if:** you have a history of coronary artery disease, high blood pressure, heart failure, arrhythmia (an abnormal or rapid heartbeat), angina (feeling pain, tightness, heaviness or pressure in the chest), or any other type of heart disease; you are currently taking any other medicines, including medicines for cancer, or if you have previously received chemotherapy treatment with medicines known as anthracyclines; you have breathing or lung problems; you are pregnant or breast-feeding; or you have side effects, see your healthcare professional. For further information on Herceptin, please talk to your healthcare professional or visit www.medsafe.govt.nz for Herceptin Consumer Medicine Information.

**Herceptin has risks and benefits.** Ask your Oncologist if Herceptin is right for you. Use strictly as directed. If symptoms continue or you have side effects, see your healthcare professional. For further information on Herceptin, please talk to your healthcare professional or visit www.medsafe.govt.nz for Herceptin Consumer Medicine Information.

Herceptin is a funded medicine for patients with HER2-positive breast cancer who meet pre-defined criteria. A prescription charge and normal Doctor’s fees may apply.

**Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:** swelling of your lips, face, tongue or throat with difficulty breathing; severe shortness of breath, difficulty breathing or wheezing; severe chest pain spreading out to the arms, neck, shoulder and/or back; rash, itching or hives on the skin; fever or chills; abnormal or irregular heartbeat; severe swelling of the hands, feet or legs; severe coughing. Possible common side effects may also include: getting tired more easily after light physical activity; shortness of breath, especially when lying down or if it disturbs your sleep; runny or blocked nose or nosebleeds; difficulty sleeping, anxiety or depression; weakness or soreness in muscles and/or joints; increased cough; feeling dizzy, tired, looking pale; flu and/or cold symptoms; frequent infections with fever, severe chills, sore throat or mouth ulcers; hot flushes; diarrhoea; changes in weight; redness, dryness or peeling of the hands or feet; unusual hair loss or thinning; nail problems; eye problems such as producing more tears, swollen runny eyes or conjunctivitis (eye infection).

Tell your doctor if:

- you have a history of coronary artery disease, high blood pressure, heart failure, arrhythmia (an abnormal or irregular heartbeat), angina (chest pain); you are currently taking any other medicines, including medicines for cancer, or if you have previously received chemotheraphy treatment with medicines known as anthracyclines; you have breathing or lung problems; you are pregnant or breast-feeding, or plan to become pregnant or breast-feed.

Tell your doctor if:

- you are currently taking any other medicines, including medicines for cancer, or if you have previously received chemotherapy treatment with medicines known as anthracyclines; you have breathing or lung problems; you are pregnant or breast-feeding, or plan to become pregnant or breast-feed.

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Herceptin SC has risks and benefits. Ask your Oncologist if Herceptin SC is right for you. Use strictly as directed. If symptoms continue or you have side effects, see your healthcare professional. For further information on Herceptin SC, please talk to your healthcare professional or visit www.medsafe.govt.nz for Herceptin SC Consumer Medicine Information.

Herceptin SC is not funded by PHARMAC. You will need to pay the full cost of this medicine. A prescription charge and normal oncologist fees may apply.

**Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:** swelling of your lips, face, tongue or throat with difficulty breathing; severe shortness of breath, difficulty breathing or wheezing; severe chest pain spreading out to the arms, neck, shoulder and/or back; rash, itching or hives on the skin; fever or chills; abnormal or irregular heartbeat; severe swelling of the hands, feet or legs; severe coughing. Possible common side effects may also include: pain or reaction at the site of your injection; getting tired more easily after light physical activity; shortness of breath, especially when lying down or being woken from your sleep with shortness of breath; runny or blocked nose or nosebleeds; difficulty sleeping; weakness or soreness in muscles and/or joints; increased cough; feeling dizzy, tired, looking pale; flu and/or cold symptoms; frequent infections with fever, severe chills, sore throat or mouth ulcers; hot flushes; diarrhoea; changes in weight; redness, dryness or peeling of the hands or feet; pain in hands or feet; unusual hair loss or thinning; nail problems; eye problems such as producing more tears, swollen runny eyes or conjunctivitis (eye infection).

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