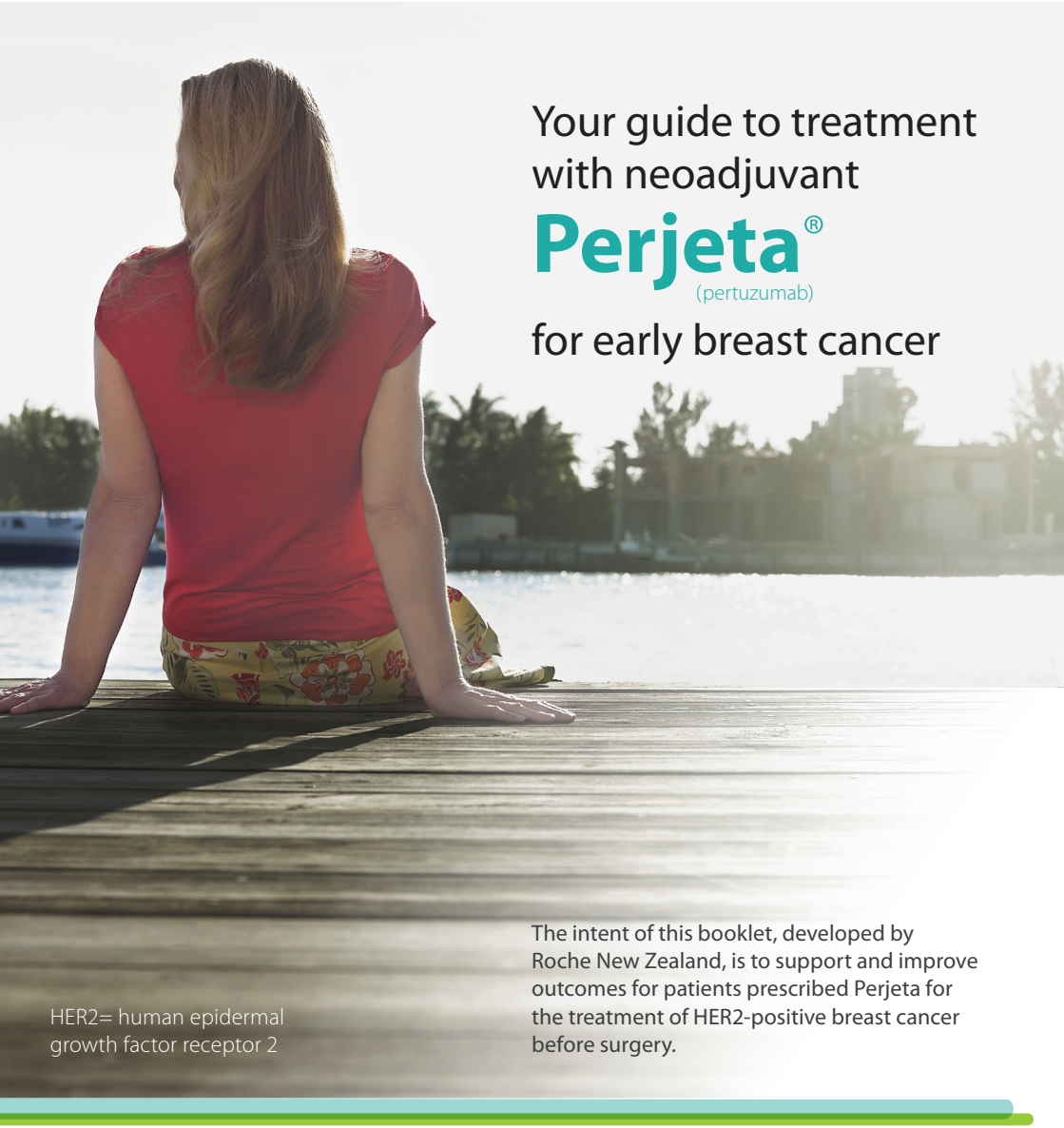


Your guide to treatment with neoadjuvant Perjeta®

(pertuzumab)

for early breast cancer

HER2= human epidermal growth factor receptor 2

The intent of this booklet, developed by Roche New Zealand, is to support and improve outcomes for patients prescribed Perjeta for the treatment of HER2-positive breast cancer before surgery.

PERJETA®
pertuzumab

This booklet is as an educational resource to help you and your whanau learn more about what to expect from treatment with Perjeta®. It does not take the place of individual advice from your healthcare professional. More information about Perjeta is available at **www.cancertreatments.co.nz** or in the Consumer Medicines Information at **medsafe.govt.nz.**

Models have been used throughout this booklet for the purpose of illustration only.

Contents

Resources

Organisations

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

Breast Cancer Foundation New Zealand

www.nzbcf.org.nz | 0800 902 732

After your diagnosis, BCFNZ offer support services services like free counselling, physio and special nurse support through their 0800 BC NURSE helpline.

Breast Cancer Aotearoa Coalition (BCAC)

www.breastcancer.org.nz

After your diagnosis, BCFNZ offer support services services like free counselling, physio and special nurse support through their 0800 BC NURSE helpline.

Cancer Society of NZ

www.cancernz.org.nz | 0800 226 237

The Cancer Society of NZ provide help and support for youand your whanau through cancer diagnosis, treatment and recovery.

All words in bold like ***this*** are explained in the glossary at the back of this booklet on page 11.

What is neoadjuvant treatment?

When medicines are given before surgery to treat cancer, the treatment is called ***neoadjuvant therapy.***

Why might neoadjuvant therapy be recommended to treat your breast cancer?

- To reduce the size of your breast cancer (tumour) if it is too big to be removed in an operation
- If you have ***inflammatory breast cancer***
- If you have ***locally advanced breast cancer***
- To reduce the size of the tumour so that you can have breast conserving surgery (lumpectomy) instead of a mastectomy (removal of the whole breast)
- To give you time to have genetic testing if you have a strong family history of breast cancer
- To give you time to consider your surgical options

A ***pathologist*** checks the breast tissue and nodes removed during surgery for a pathologic response. This describes how much of the cancer is left in the breast and ***lymph nodes***.

In some cases, neoadjuvant therapy will shrink the tumour so much that the pathologist can't detect any remaining cancer. This is called a ***pathologic complete response (pCR)***.

A pCR can give some information about long term outcomes. Although a pCR is good news, it doesn't mean the cancer will never return. Also, many people who don't have a pCR will still do very well.

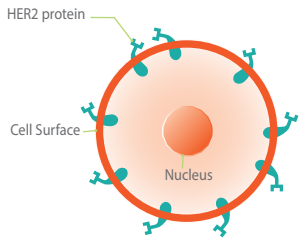
What is HER2-positive breast cancer?

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.

HER2 is a protein found on the surface of all normal cells in your body, like the cell shown below

Normal cell in your body

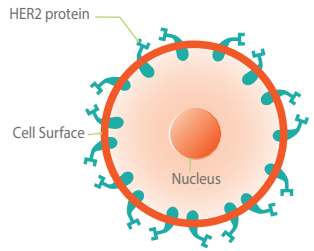


The HER2 protein tells the cell how to grow and split to reproduce

About 1 in 5 women diagnosed with breast cancer are HER2-positive

When too many HER2 proteins grow on the surface of a cell, the cell becomes abnormal, like the cell shown below

Abnormal cell with too many HER2 proteins



The extra HER2 proteins tell the cell to split and reproduce much faster than normal. This abnormal cell makes other abnormal cells and they go on to make even more abnormal cells. This process happens many times and that is how HER2-positive breast cancer develops

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 called a tumour.

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.

Neoadjuvant treatment of HER2-positive breast cancer with Perjeta®

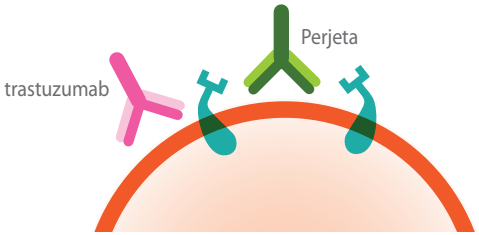
Perjeta is a HER2-targeted therapy

Perjeta is a medicine for the treatment of ***HER2-positive breast cancer***. It is a ***targeted therapy*** that is given as an ***IV infusion***. Perjeta fights cancer cells that have too much HER2 and is designed to cause less harm to normal cells.

Normal cells also have HER2 (just not as much), so HER2-targeted therapies can also affect healthy cells and cause side effects, including serious side effects. Please see page 9 for additional safety information.

In New Zealand, Perjeta can be used in combination with trastuzumab and chemotherapy as treatment of HER2-positive breast cancer before surgery.

Perjeta and trastuzumab target HER2



- *Perjeta and trastuzumab target the HER2 protein in different ways*
- *When used together, Perjeta and trastuzumab provide a dual blockade to stop HER2 signals helping to shrink the tumour*

Why is Perjeta® used as neoadjuvant therapy?

Two clinical trials looked at how well Perjeta worked in combination with ***trastuzumab*** and chemotherapy when given before surgery.

One of these showed that nearly 40% of people receiving the combination of Perjeta, trastuzumab and chemotherapy had no evidence of tumour tissue detectable at the time of surgery (known as a ***pathological complete response, or pCR)*** compared to 21.5% of people who received trastuzumab and chemotherapy.

39.3% Of patients treated with **Perjeta, trastuzumab**, and **chemotherapy** had a pCR

VS

21.5% Of patients treated with **trastuzumab** and **chemotherapy** had a pCR

How is Perjeta® administered?

Perjeta is given in combination with trastuzumab and chemotherapy.

Perjeta is given as an ***IV infusion***, which means that the medicine is administered through a needle that your nurse inserts into a vein.

If you haven't received an infusion before, you can ask your doctor or nurse to explain this to you in more detail.

Perjeta is typically given every 3 weeks on the same day as trastuzumab and chemotherapy. Your doctor will decide how many infusions you will be given.

Your first infusion

- The amount of medicine you are given and how long each infusion will last are different for the first and following infusions for Perjeta.
- The medicines are given more slowly during your first visit. Your first dose of Perjeta will be given as an IV infusion over 60 minutes. You will be monitored for 30-60 minutes after your Perjeta infusion.

Your subsequent infusions

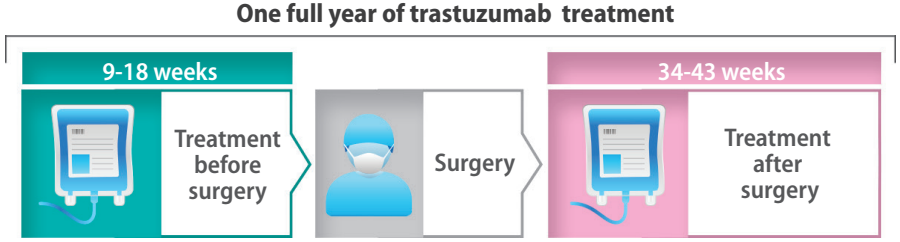
- If the first infusion is well tolerated, subsequent infusions may be given over 30 minutes. This will be followed by a 30 to 60 minutes observation time.
- The infusion may be slowed or interrupted if you experience side effects or have an allergic reaction. Your doctor will decide on the infusion time that is right for you.

Preparing for an infusion

- Bring something to help pass the time, like a magazine or book, or music to listen to during your infusion
- If you're unsure about driving, ask a friend or family member to drive you home after your infusion

What is a complete treatment course for HER2-positive early breast cancer?

- Before surgery (neoadjuvant), Perjeta® is given with trastuzumab and chemotherapy.
- After surgery (***adjuvant***), trastuzumab is given to complete a total of 1 year of treatment (time before and after surgery).



- Sometimes other medicines are also given with trastuzumab after surgery.

It's important to ask questions

It is important you ask questions and fully understand the options you have before you make any decisions.

If you're not sure where to start, a sample list of questions you may want to ask your doctor is listed on page 10 of this booklet.

Possible side effects with Perjeta®

All medicines can have side effects. Sometimes they are serious, most of the time they are not. It is important to know what side effects may happen and what symptoms you should watch out for. This section of the booklet outlines some of the most common side effects you may experience while on Perjeta treatment. Because Perjeta 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 Perjeta or due to the other medicines.

During an infusion:

Tell your doctor or nurse immediately if you notice any of the following while receiving an infusion (particularly during the first infusion):

- swelling of your face, lips, tongue or throat with difficulty breathing,
- severe swelling of other parts of your body such as your hands or feet
- severe shortness of breath, wheezing or trouble breathing
- severe chest pain, spreading out to the arms, neck, shoulder or back
- abnormal or irregular heartbeat
- rash, itching or hives on the skin
- fever or chills
- severe coughing

These may be serious side effects. You may need medical attention.

After an infusion:

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- swelling of your face, lips, tongue or throat with difficulty breathing,
- severe swelling of your hands or feet
- severe shortness of breath, wheezing or trouble breathing
- severe chest pain, spreading out to the arms, neck, shoulder or back
- abnormal or irregular heartbeat
- rash, itching or hives on the skin
- fever or chills
- severe coughing

Tell your doctor or nurse as soon as possible if you notice any of the following:

- any of the side effects listed above
- diarrhoea (loose or frequent stools) or constipation
- indigestion or stomach pain
- sore mouth, throat or gut
- getting tired more easily after light physical activity, such as walking
- shortness of breath especially when lying down or being woken from your sleep with shortness of breath
- nail problems especially inflammation where the nail meets the skin
- hair loss
- feeling dizzy, tired, looking pale
- hot flushes
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- nose bleeds
- eye problems such as producing more tears
- insomnia (trouble sleeping)
- weak, numb, tingling, prickling or painful sensations mainly affecting the feet and legs
- loss of appetite, loss of or altered taste
- joint or muscle pain, muscle weakness

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. Others may occur in some people and there may be some side effects not yet known.

For more detailed information on side effects you can also check out the consumer medicine information at: **www.medsafe.govt.nz**

Ask your healthcare team if you have any specific questions on side effects with your treatment.

Questions you may want to ask your healthcare team

To better understand your treatment plan, it may help to have a discussion with someone on your healthcare team who you're comfortable with. Here are some common questions to help you get started.

- Is treatment before surgery right for me?
- What can I expect during neoadjuvant treatment?
- Is Perjeta® the right treatment choice for my type of breast cancer?
- How is Perjeta different from trastuzumab?
- How is Perjeta different from chemotherapy?
- What do I need to do to prepare for my infusion?
- How long do I need to receive Perjeta?
- How long do I need to receive chemotherapy?
- What treatment options are available to me after surgery?
- What side effects should I expect, and how severe might they be?
- Are there methods to help manage certain side effects?
- How can I tell if the treatment is working?
- Is Perjeta recommended during pregnancy?

Perjeta for the treatment of HER2-positive breast cancer before surgery is not funded by PHARMAC.

Roche New Zealand has a *Cost Share Programme* for Perjeta which offers assistance with the cost of your medicine. There are criteria for enrolling into the Cost Share Programme and your doctor can you give you the details.

Glossary

Adjuvant therapy:
Additional treatment for early breast cancer that is given after the main treatment (usually surgery) that may include radiation therapy, ***chemotherapy, hormonal therapy,*** or ***targeted therapy***

Chemotherapy:
A type of medicine that kills cells that grow and divide rapidly; these can include cancer cells or fast-growing normal cells

Cost Share Programme:
A programme designed to assist patients access to non-PHARMAC funded medicines by making them more affordable for the patient

HER2-positive:
When breast cancer cells have too many HER2 receptors, the disease is called HER2-positive or "HER2+" breast cancer

HER2 receptor:
A type of protein that is found on the surface of cells in everyone. This protein tells cells to grow and divide. Too much HER2 is called "HER2 overexpression" and may result in the cells growing and dividing more quickly

Inflammatory breast cancer:
A rare form of invasive breast cancer that affects the lymphatic vessels in the skin of the breast, causing the breast to become red and inflamed

IV (infusion):
A method of administering a drug by inserting a needle into your vein. Also known as an IV infusion, which means that medicine is slowly given directly into the bloodstream through a vein

Locally advanced breast cancer:
When the cancer cells have spread from the breast to the chest wall or the skin of the breast, or to many ***lymph nodes*** in the underarm area

Lymph nodes:
Glands in the armpit and other parts of the body that filter and drain lymph fluid, trapping bacteria, cancer cells and other particles that could be harmful to the body

Monoclonal antibodies:
Antibodies produced outside the body that are designed to target specific substances using the body's natural immune defences.

Neoadjuvant therapy/treatments:
Treatment given prior to surgery

Pathologist:
A specialist who studies the causes and effects of diseases, and who also examines laboratory samples of body tissue for diagnostic or forensic purposes

Pathological complete response (pCR):
Pathological complete response is achieved when no cancer cells are detected in the breast tissue following surgery

Perjeta® (pertuzumab):
A ***monoclonal antibody*** that targets the protein ***HER2***, which is found on the surface of some cancer cells. Perjeta is a treatment for breast cancer that that spread, has come back in the breast and also pre surgery

PHARMAC
The Pharmaceutical Management Agency. This is the New Zealand Crown agency that decides, on behalf of Te Whatu Ora - Health New Zealand, which medicines and related products are subsidised for use in the community and public hospitals

Subcutaneous (SC):
Given under the skin

Targeted therapy:
A type of medicine that is designed to attack specific cancer cells and can also affect healthy cells

Trastuzumab:
Is a targeted therapy that targets and kills cancer cells that make too much HER2 protein.

Notes

For any questions about this booklet or Perjeta® (pertuzumab) contact Roche Medical Information on 0800 276 243 or via medinfo.roche.com.

If you are pregnant or plan to become pregnant, Perjeta may be harmful to an unborn baby. If there is a need for Perjeta treatment when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby. You should use effective contraception to avoid becoming pregnant while you are being treated with Perjeta and for 7 months after stopping treatment.

If you become pregnant while receiving Perjeta or within 7 months following the last dose of Perjeta, please contact your oncologist for medical advice. Report the pregnancy to Roche Patient Safety at nz.drugsafety@roche.com or 0800 276 243.

Additional information will be requested during a Perjeta-exposed pregnancy and the first year of the infant's life. This will enable Roche to better understand the safety of Perjeta and to provide appropriate information to health authorities, healthcare providers, and patients.

For additional information, please refer to the Perjeta Consumer Medicine Information at www.medsafe.govt.nz

Perjeta® (pertuzumab), 420mg vial, is a **Prescription Medicine** used to treat breast cancer before surgery (neoadjuvant), after surgery (adjuvant) or metastatic (spreading) breast cancer. It is only used for patients whose tumour has tested positive to HER2.

Tell your doctor if: you have a history of heart problems such as heart failure, cardiac arrhythmias (an abnormal or rapid heartbeat), poorly controlled high blood pressure, or a recent heart attack; you have previously received chemotherapy treatment with medicines known as anthracyclines; you have experienced heart problems during previous treatment with Herceptin (trastuzumab); you have inflammation of the digestive tract, e.g. sore mouth or diarrhoea; you are allergic to any other medicines or any other substances such as foods, preservatives or dyes; you are pregnant or breast-feeding, or plan to become pregnant or breast-feed; you are currently taking any other medicines.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following: swelling of your face, lips, tongue or throat with difficulty breathing; swelling of other parts of your body such as your hands or feet; shortness of breath, wheezing or trouble breathing; severe chest pain, spreading out to the arms, neck, shoulder or back; abnormal or irregular heartbeat; rash, itching or hives on the skin; feeling sick (nausea); headache; fever or chills or severe coughing. **Possible common side effects may also include:** diarrhoea (loose or frequent stools) or constipation; indigestion or stomach pain; sore mouth, throat or gut; 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; nail problems; hair loss; feeling dizzy, tired, looking pale; hot flushes; frequent infections with fever, severe chills, sore throat or mouth ulcers; nose bleeds; eye problems such as producing more tears; insomnia (trouble sleeping); weak, numb, tingling, prickling or painful sensations mainly affecting the feet and legs; loss of appetite; loss of or altered taste; joint or muscle pain or muscle weakness.

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

Perjeta is a funded medicine for patients with HER2-positive metastatic breast cancer who meet pre-defined criteria.

Perjeta is not a PHARMAC funded medicine for the neoadjuvant or adjuvant treatment of early breast cancer.

A prescription charge and normal Doctor's fees may apply.

Consumer panel dated May.2020
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