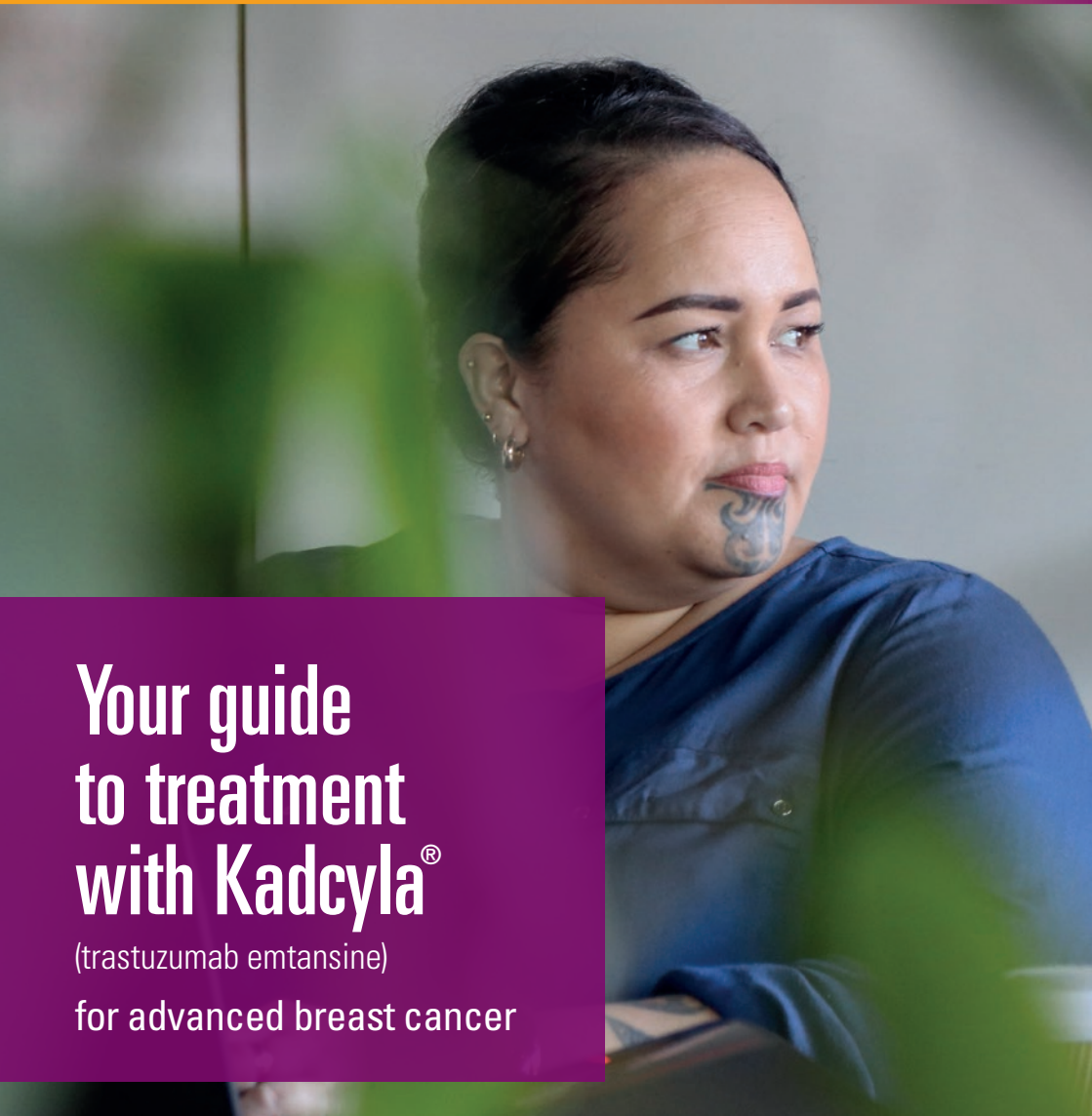




Your guide to treatment with Kadcyła[®]

(trastuzumab emtansine)
for advanced breast cancer

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



Kadcyła[®]
trastuzumab emtansine

What is this booklet about?

This booklet is for people who have HER2-positive breast cancer that has spread to other areas of their body. This is known as advanced breast cancer, metastatic breast cancer or secondary breast cancer. These different terms can be confusing, so we will call it advanced breast cancer throughout this booklet.

You are receiving this booklet because your healthcare professional has prescribed you a medicine called Kadcyla, also known as trastuzumab emtansine for the treatment of HER2-positive advanced breast cancer. This booklet is as an educational resource to help you and your whanau learn more about what to expect from treatment with Kadcyla.

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Understanding advanced breast cancer

When it comes to our health, we all have different information needs. Some people like to know everything about their condition, whereas others prefer to know very little. This section covers a general explanation of advanced breast cancer. Your doctor will be able to provide you with more information that is relevant to you and your cancer.

What is advanced breast cancer?

Advanced breast cancer means the cancer has spread beyond the breast, underarm area and internal mammary lymph nodes.

Breast cancer is caused by abnormal cell growth. When the abnormal cells split and reproduce they form a tumour in the breast area.

Sometimes the abnormal cells can break away from the breast tumour and move to other parts of the body, spreading the cancer. This includes bones, liver, lungs and the brain.

The types of symptoms you experience with advanced breast cancer will depend on where the cancer has spread.

There are a number of treatments for advanced breast cancer available in New Zealand. These treatments can help manage symptoms and slow down the spread of advanced breast cancer. Kadcyla is one of these treatments.

What is HER2-positive breast cancer?

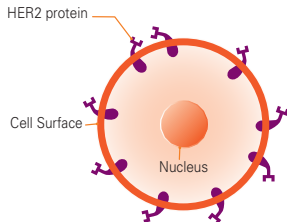
Research has shown us that there is not just one type of breast cancer. This means the abnormal cells in one tumour can look and act differently to the abnormal cells in another tumour.

HER2-positive breast cancer is an example of one type of breast cancer.

What is HER2?

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

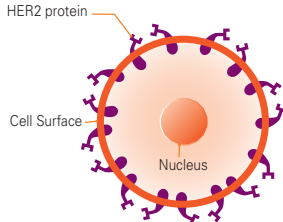
Normal cell in your body



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

But 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

HER2 stands for:
Human Epidermal
Growth Factor
Receptor Type 2

HER2-positive
is often written
as **HER2+**

HER2-negative
is often written
as **HER2-**

About **1 in 5** women
diagnosed with breast
cancer in New Zealand
are **HER2-positive**.



Introducing Kadcyla for the treatment of advanced breast cancer

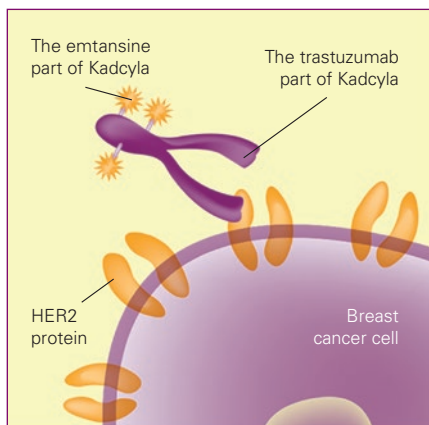
You may already have received prior treatment for the treatment of your HER2-positive advanced breast cancer. Because trastuzumab is a ‘targeted therapy’, it only acts on breast cancer cells with too much of the HER2 protein. Chemotherapy is not a ‘targeted therapy’ and may also damage normal cells that divide rapidly (for example, cells of the mouth, digestive system, skin and hair).

Kadcyla is a combination of trastuzumab and chemotherapy given as a single treatment. This type of treatment is called an ‘antibody-drug conjugate’.

By joining these two treatment types together, Kadcyla delivers chemotherapy only to cells that contain too much of the HER2 protein. This means Kadcyla is designed to minimise the effects of chemotherapy on healthy cells in your body.

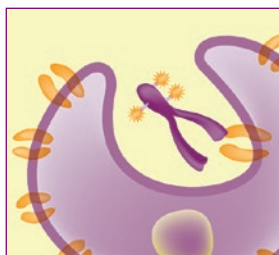
The trastuzumab part of Kadcyla works by attaching to HER2 proteins on breast cancer cells. This reduces the stimulus for cancer cells to divide and grow. The trastuzumab part of Kadcyla may also encourage the body’s own immune cells to help destroy the cancer cells.

The chemotherapy part of Kadcyla is called emtansine. As it is attached to trastuzumab, emtansine is delivered into breast cancer cells that have too much of the HER2 protein on their surface. By releasing the emtansine chemotherapy directly into the breast cancer cells, Kadcyla delivers chemotherapy where it’s needed.



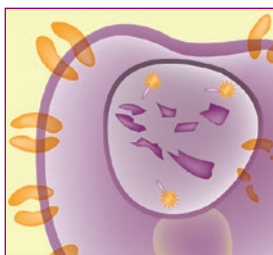
Step 1

During treatment, Kadcyła attaches to HER2 proteins on HER2-positive breast cancer cells. This tells the cancer cells to stop growing and signals the body's immune system to destroy these cells.



Step 2

Next, Kadcyła goes inside the cancer cells.



Step 3

Inside the cancer cell the trastuzumab part breaks up, releasing the chemotherapy emtansine.



Step 4

The chemotherapy emtansine attaches to structures inside the cancer cell that help it grow. This stops the cancer cell's ability to grow and divide, eventually leading to cancer cell death.

How is Kadcylla given?

Kadcyla is prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.

Your first dose

The first IV infusion will be given over 90 minutes. Your doctor or nurse will then observe you for any signs or symptoms of an infusion reaction for 90 minutes after your infusion is complete.

Your subsequent doses

Kadcyla is given every three weeks. If the first infusion was well tolerated, your next infusion time may be shortened to 30 minutes. This will usually be followed by an additional 30 minutes observation time. The number of infusions you will be given depends on how you respond to treatment. Your doctor will decide on the Kadcyla infusion duration and dose that is right for you.

Your first dose



Your subsequent doses



The infusion time and dose of Kadcyla may vary from person to person and also depends on how you respond to treatment.



Possible side effects of Kadcyla treatment

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 Kadcyla treatment.

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
- swelling of other parts of your body such as your hands or feet
- shortness of breath, wheezing or trouble breathing
- abnormal or irregular heartbeat
- rash, itching or hives on the skin
- flushing (warm, red) skin
- pain or swelling at site of injection
- feeling sick (nausea) or vomiting, diarrhoea
- pain or discomfort (including stomach pain, back pain, chest or neck pain)
- fever or chills
- headache
- fatigue or tiredness
- cough

These may be serious side effects. You may require urgent 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:

- any of the side effects listed above
- swelling of ankles or legs
- weight gain of more than 2 kilograms in 24 hours
- dizziness or fainting
- increased cough
- shortness of breath, especially when lying down or being woken from your sleep
- abdominal pain
- jaundice (your skin and whites of your eyes look yellow)
- dark urine
- rash, itching or hives on the skin
- loss of appetite

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

- getting tired more easily after light physical activity, such as walking
- insomnia (difficulty sleeping)
- weakness, soreness in muscles and/or joints
- numbness or weakness of arms and legs
- bleeding or bruising more easily than normal
- nose bleeds
- bleeding from gums
- feeling dizzy, tired, looking pale
- flu and/or cold like symptoms, frequent infections such as fever, severe chills, sore throat or mouth ulcers
- dry mouth
- taste disturbance or loss of taste
- constipation
- vomiting
- indigestion
- diarrhoea
- eye problems such as producing more tears, swollen runny eyes or conjunctivitis (discharge with itching of the eyes and crusty eyelids).

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor, nurse or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

For more detailed information on side effects ask your doctor or check out the consumer medicine information leaflet at www.cancertreatments.co.nz

Support from your healthcare team

Being given information

Some people like to know every detail about their diagnosis and treatment. Having all that information is what helps them to cope better. Other people just want to know the smallest amount. Knowing very little is what helps them to cope better. These are both valid ways of coping. However your doctor won't necessarily know what you prefer. So it can be helpful to think about how you would like to receive and digest information. Then you can guide your healthcare team on how much information they should give you.

Asking questions

It is really normal for people to go into their doctor's office and then forget all the questions they had in their head. It is important for you to get the answers to those questions. So it can be helpful to write them down as they come up and then take that list with you when you see your doctor. On page 27 you can find a list of questions to ask your doctor that you may find useful.

Talking to your doctors about non-medical things

Even though your healthcare team is there to look after your medical needs, it is also important for them to know how you are coping in general. A lot of things can change at a time like this. There might be changes to your finances, your ability to get around at home or your emotional well-being. Your doctor might not be able to help you directly but they will probably be able to refer you on to someone that can.

Support from Patient Support Groups

New Zealand has a lot of Patient Support Groups that exist to support people and their families through difficult times. There are a number of organisations that can support people with breast cancer. This is another way of getting support during this time and they offer many different services from providing information to nursing and psychological support.

These organisations include:



Sweet Louise

www.sweetlouise.co.nz

0800 112 277

Sweet Louise helps to improve the quality of life for women and men living with advanced breast cancer. They offer information, advice, support and a range of practical and therapeutic services.



Breast Cancer Aotearoa Coalition (BCAC)

www.breastcancer.org.nz

BCAC provides information, support and representation, empowering people with a breast cancer diagnosis, to make informed choices about their treatment and care.



Breast Cancer Foundation New Zealand (BCFNZ)

www.nzbcf.org.nz

0800 902 732

BCFNZ provides information, support and representation, empowering people with a breast cancer diagnosis, to make informed choices about their treatment and care.



Cancer Society of NZ

www.cancernz.org.nz

0800 226 237

Questions to ask your doctor

Below is a useful list of questions you may want to ask your doctor at your next appointment.

Questions to ask about your diagnosis

- + What kind of breast cancer do I have?
- + What stage is my cancer and how does it affect my treatment plan?
- + Has my tumour been tested for HER2?
- + If so, is my cancer HER2-positive?
- + What is the time frame for me to make decisions regarding my treatment?

Questions about your treatment

- + What are my treatment options?
- + How long will I need to stay on these treatments?
- + How will I know this treatment is working?
- + If I decide to have treatment, when can I start?

Questions about Kadcyla

- + How does Kadcyla differ from other treatments?
- + What side effects can I expect to have?
- + What can I do to help manage the side effects?

Kadcyla® (trastuzumab emtansine), 100mg and 160mg vials, is a **Prescription Medicine** used to treat patients with early breast cancer following surgery and patients with advanced or metastatic breast cancer (i.e. the cancer has spread to areas near the breast or to other parts of the body). It is only used for patients whose tumour has tested positive to HER2.

Tell your doctor if: you have had a serious infusion-related reaction to Herceptin (trastuzumab); you have a history of heart problems; you have any breathing or lung problems; you have liver problems; you have bleeding problems; you are receiving anti-coagulant treatment (blood thinning medication); 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 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 lips, face, tongue or throat with difficulty breathing; swelling of other parts of your body such as your hands, legs, ankles or feet; weight gain of more than 2 kilograms in 24 hours after an infusion; shortness of breath (especially when lying down, being woken from your sleep or when exercising); wheezing or trouble breathing; abnormal or irregular heartbeat; rash, itching or hives on the skin; flushing (warm, red) skin; pain or swelling at the site of injection; feeling sick (nausea) or vomiting; diarrhoea; pain or discomfort (including stomach pain, back pain, chest or neck pain); fever or chills; headache; fatigue or tiredness; cough; dizziness or fainting; jaundice; dark urine; or loss of appetite. **Possible common side effects may also include:** getting tired more easily after light physical activity such as walking; insomnia (difficulty sleeping); weakness, soreness in muscles and/or joints; numbness or weakness of arms and legs; bleeding or bruising more easily than normal; nose bleeds, bleeding from gums; feeling dizzy, tired, looking pale; flu and/or cold like symptoms, frequent infections such as fever, severe chills, sore throat or mouth ulcers; dry mouth; taste disturbance or loss of taste; constipation, vomiting, indigestion or diarrhoea; or eye problems such as producing more tears, swollen runny eyes or conjunctivitis.

Kadcyla has risks and benefits. Ask your Oncologist if Kadcyla is right for you.

Use strictly as directed. If symptoms continue or you have side effects, see your healthcare professional. For further information on Kadcyla, please talk to your health professional or visit www.medsafe.govt.nz for Kadcyla Consumer Medicine Information.

Kadcyla is a PHARMAC funded medicine for patients with HER2-positive metastatic breast cancer and from 1 July 2022, for the adjuvant treatment of HER2-positive early breast cancer in patients who meet pre-defined criteria.

Roche Products (New Zealand) Limited, Auckland. Phone: 0800 656 464. www.roche.co.nz

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PV Pregnancy Program

If you are pregnant or plan to become pregnant, Kadcyla may be harmful to an unborn baby. If there is a need for Kadcyla 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 Kadcyla and for 7 months after stopping treatment.

If you become pregnant while receiving Kadcyla or within 7 months following the last dose of Kadcyla, 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 Kadcyla-exposed pregnancy and the first year of the infant's life. This will enable Roche to better understand the safety of Kadcyla and to provide appropriate information to health authorities, healthcare providers, and patients.

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

