Kadcyla®
trastuzumab emtansine

Roche

Your Guide to Kadcyla®

trastuzumab emtansine

for the treatment of HER2-positive early breast cancer

Kadcyla is used to treat early HER2-positive breast cancer following surgery.

About this booklet

Your doctor has prescribed Kadcyla® (trastuzumab emtansine) for the treatment of your HER2-positive early breast cancer after surgery. People who have received treatment before surgery with specific anti-cancer medicines, and then have some remaining cancer cells found in their breast tissue during surgery, are eligible to receive Kadcyla.

This booklet has been developed to help you understand more about your treatment with Kadcyla, and how it works for your type of cancer.

The information provided should not replace the advice of your doctor or other healthcare professionals. If you have any questions about your treatment or your condition, you should discuss these with your oncologist.

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When is Kadcyla given?

Kadcyla is used for the treatment of HER2-positive early breast cancer after surgery in people who have already received specific anti-cancer medicines, and have some remaining cancer cells found in their breast tissue during surgery.

BEFORE SURGERY

The goal of the treatment is to shrink the cancer before surgery

SURGERY

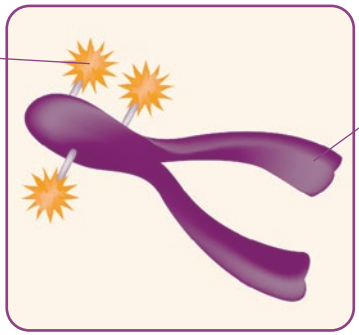
AFTER SURGERY

The goal of the treatment is to remove any cancer cells left behind after surgery

What is Kadcyla?

Kadcyla is a combination of two anti-cancer medicines: a specific treatment for HER2-positive breast cancer called trastuzumab, and a chemotherapy.

The **chemotherapy** part of Kadcyla



The **trastuzumab** part of Kadcyla

Kadcyla combines two cancer-fighting treatments in one: the HER2-targeted therapy trastuzumab plus chemotherapy.

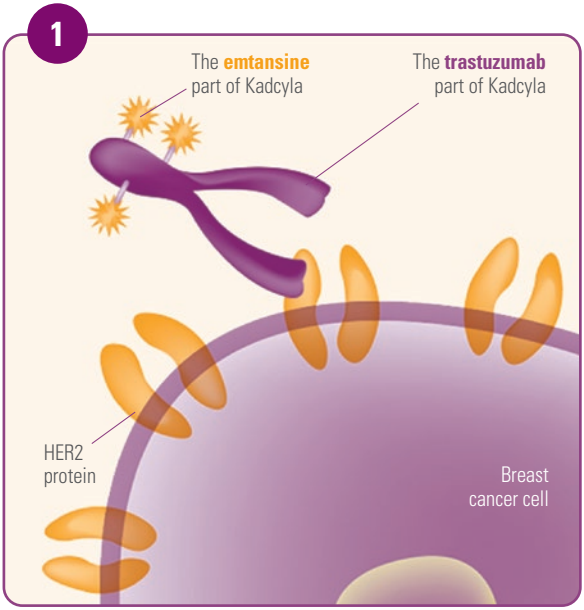
The trastuzumab part of Kadcyla

The trastuzumab part of Kadcyla works by attaching to particular proteins (called HER2), which are found in large amounts on the surface of some breast cancer cells. By doing this, it interferes with the growth of these cancer cells. The trastuzumab part of Kadcyla may also encourage the body's own immune cells to help destroy the cancer cells.

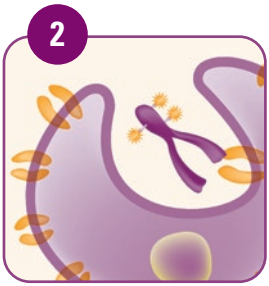
The chemotherapy part of Kadcyla

The chemotherapy part of Kadcyla is called emtansine. By being attached to trastuzumab, it is carried directly into breast cancer cells that have HER2 proteins on their surface, and acts to stop the growth and spread of these cells. By delivering this chemotherapy directly into the breast cancer cells, the chemotherapy part of Kadcyla is able to act in a targeted way.

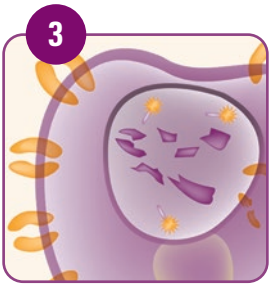
How does Kadcyla work?



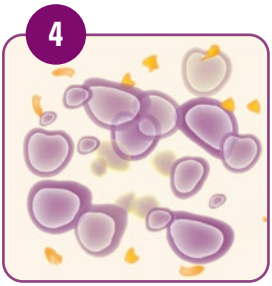
During treatment, Kadcyla attaches to HER2 proteins on HER2-positive breast cancer cells. This tells the cancer cells to stop growing and signals the body's immune system to destroy these cells.



Next, Kadcyla goes inside the cancer cells.



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



By delivering the chemotherapy emtansine directly inside HER2-positive cancer cells, Kadcyla helps to stop the growth and spread of the cancer cells.

How is Kadcyla given?

Your Kadcyla treatment will be prepared by a healthcare professional and will be administered in a hospital or clinic by your doctor or nurse.

Like many cancer treatments, Kadcyla is given by intravenous (IV) infusion, meaning that it will be delivered through a needle that a nurse inserts into your vein.

Your first dose

Your first infusion will be given over 90 minutes. Your doctor or nurse will then observe you for any signs or symptoms of a reaction for 90 minutes after your infusion is complete (see page 10 of this booklet).

Your subsequent doses

Kadcyla will be given to you every three weeks for 14 rounds of treatment (called cycles), unless your cancer comes back or side effects require you to stop treatment sooner.

If you are able to tolerate the first infusion well, your next infusion time may be shortened to 30 minutes. This will usually be followed by an additional 30 minutes observation time.

Your first dose

Kadcyla infusion | Observation time

Your subsequent doses

Kadcyla infusion | Observation time

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. You may need medical treatment if you get some of the side effects.

Your treatment with Kadcyla may need to be stopped or the dose reduced if you experience any of the side effects listed in this booklet. Tell your doctor or nurse as soon as possible if you do not feel well while you are receiving Kadcyla.

During an infusion

Some patients experienced reactions during the time of their infusion with Kadcyla in clinical trials. Most reactions were mild to moderate in intensity, and most resolved after Kadcyla treatment was withdrawn. Tell your doctor or nurse immediately if you notice any of the following during your 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

Tell your doctor or nurse as soon as possible if you do not feel well while you are receiving Kadcyla. Your doctor or nurse may need to delay, reduce the dose or discontinue Kadcyla if you experience an infusion reaction. Urgent medical attention may also be required.

After an infusion

Contact your doctor immediately or go to the Emergency Department at your nearest hospital if you notice any symptoms of infusion reactions (listed previously) after an infusion.

You should also tell your doctor or nurse as soon as possible if you notice any of the following symptoms after an infusion:

- 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)

Other symptoms

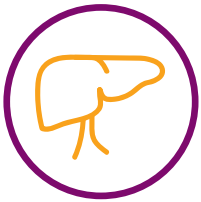
The lists on the previous pages do not include all possible side effects.Your doctor or pharmacist has a more complete list. Other side effects may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list, and ask your doctor, nurse or pharmacist if there is anything you don't understand. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Monitoring during your treatment with Kadcyla

Your doctor may delay, reduce or discontinue your Kadcyla treatment if you experience liver, heart, bleeding or lung problems during your treatment.

Kadcyla has been associated with liver, heart, bleeding and lung problems in some patients in clinical trials. Your doctor or nurse will take regular blood tests to monitor your liver function, cells and proteins in your blood before each Kadcyla infusion. Likewise, your heart function may be monitored prior to starting therapy and every few months during your treatment with Kadcyla.



Symptoms of liver problems

- Abdominal pain
- Jaundice (your skin and whites of your eyes look yellow)
- Dark urine
- Rash, itching or hives on the skin
- Loss of appetite

Symptoms of heart problems

- Swelling of the ankles or legs
- Weight gain of more than 2 kg in 24 hours
- Dizziness or fainting
- Increased cough
- Shortness of breath, especially when lying down or being woken from your sleep

Symptoms of lung problems

- Chest pain, especially if it worsens with breathing

Support organisations

When going through treatment for breast cancer, it is important to find support and resources that help you stay focused on your treatment and overall health. The following resources may be helpful to you. Be sure to talk to your doctor or nurse about other sources of support.

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 New Zealand

www.cancernz.org.nz
0800 226 237

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 get you started. You can use the following pages to take notes.

- What do I need to do to prepare for my infusion?
- How long do I need to be on Kadcyla?
- Do I need to have regular blood tests?
- How often will I need to attend appointments during my treatment with Kadcyla?
- 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?

Notes

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

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

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