Kadcyla®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using Kadcyla?

Kadcyla contains the active ingredient trastuzumab emtansine. Kadcyla is used to treat early HER2-positive breast cancer following surgery and advanced or metastatic HER2-positive breast cancer, i.e. the cancer has spread to areas near the breast or to other parts of your body. For more information, see Section 1. Why am I using Kadcyla? in the full CMI.

2. What should I know before I use Kadcyla?

Do not use if you have ever had an allergic reaction to trastuzumab emtansine or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section 2. What should I know before I use Kadcyla? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Kadcyla and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is Kadcyla given?

Kadcyla is given by a slow drip into a vein (intravenous (IV) infusion) by a doctor or nurse once every three weeks. The first infusion will be over 90 minutes. If the first infusion is well tolerated, your drip time may be shortened to 30 minutes. More instructions can be found in Section 4. How is Kadcyla given? in the full CMI.

5. What should I know while using Kadcyla?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are receiving Kadcyla. Be sure to keep all of your appointments with your doctor so that your progress can be checked.
Things you should not do	• Do not stop using this medicine without speaking to your doctor first. • Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Kadcyla affects you.

For more information, see Section 5. What should I know while using Kadcyla? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with Kadcyla. It is important to be aware of them so that you can identify any symptoms if they occur. Tell your doctor or nurse immediately or go to the nearest hospital Emergency Department if you experience signs or symptoms of a serious allergic reaction such as fever or chills, swelling of the face, lips, tongue, throat or other parts of the body, dizziness or fainting, trouble breathing or wheezing, coughing, rash, itching or hives on the skin.

Some other serious side effects of Kadcyla include burning sensation or tenderness at the site of injection, nausea, vomiting, diarrhoea, pain or discomfort, fatigue, bleeding or bruising, dark urine or yellowing of your skin and eyes.

Tell your doctor or nurse immediately or go to the Emergency Department if you experience any of these side effects. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: Do not substitute Kadcyla for or with trastuzumab.

In order to prevent medication errors, check the vial labels to ensure the medicine being prepared and administered is Kadcyla (trastuzumab emtansine) and not trastuzumab.

Kadcyla®

Active ingredient(s): *trastuzumab emtansine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Kadcyla. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Kadcyla.**

Where to find information in this leaflet:

1. Why am I using Kadcyla?

Kadcyla contains the active ingredient trastuzumab emtansine. Kadcyla belongs to a group of medicines known as anti-neoplastic (or anti-cancer) agents.

Kadcyla is made up of two substances:

- trastuzumab - a monoclonal antibody which recognises and attaches to a protein called human epidermal growth factor receptor 2 (HER2). HER2 is found in large amounts on the surface of some cancer cells. Monoclonal antibodies are proteins made in a laboratory. These proteins are designed to recognise and bind to other unique proteins in the body.
- emtansine - an anti-cancer substance.

Kadcyla is designed to target and deliver the anti-cancer emtansine directly inside HER2-positive cancer cells to stop the growth and spread of the cancer cells.

Kadcyla is used to treat the following stages of HER2-positive breast cancer:

- **early breast cancer following surgery.**
- **advanced or metastatic breast cancer, i.e the cancer has spread to areas near the breast or to other parts of your body.**

It is only used in patients whose tumour has tested positive to HER2. You may have previously received HER2 targeted therapies.

2. What should I know before I use Kadcyla?

Warnings

Do not use Kadcyla if:

- you are allergic to trastuzumab emtansine, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if:

- **you have had a serious infusion-related reaction to trastuzumab**
- **you have a history of heart problems.**

  Your doctor will monitor your heart function closely before and during your treatment with Kadcyla.
- **you have any breathing or lung problems**
- **you have liver problems**
- **you have bleeding problems**
- **you are receiving anti-coagulant treatment (blood thinning medications) e.g. warfarin, heparin or low molecular weight heparin**

Kadcyla can lower the number of platelets in your blood. Platelets help your blood to clot so you might get unexpected bleeding (such as nose bleeds, bleeding from gums). Your doctor or nurse will monitor your platelet levels during your treatment with Kadcyla.

- **take any medicines for any other condition**
- **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes**

  Allergic and/or anaphylactic reactions can occur with Kadcyla treatment (known as infusion related reactions). Your doctor or nurse will check for side effects during your infusion.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not use Kadcyla if you are pregnant. Kadcyla may be harmful to your unborn baby.

Your doctor will advise you about using effective contraception to avoid you or your partner becoming pregnant while you are being treated with Kadcyla and for at least 7 months after stopping treatment. It is not known if Kadcyla affects the ability of a woman to become pregnant. Discuss any future child bearing plans with your doctor before starting Kadcyla.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if Kadcyla passes into breast milk. It is recommended that you discontinue breast-feeding while you are being treated with Kadcyla and not start breast-feeding until 7 months after completing Kadcyla treatment.

If you have not told your doctor about any of the above, tell them before you are given Kadcyla

Use in children

The safety and effectiveness of Kadcyla in children under 18 years of age have not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Kadcyla and affect how it works.

- Oral antifungal medications, e.g. ketoconazole, itraconazole, voriconazole
- Some antibiotics used to treat bacterial infections, e.g. clarithromycin
- Some medicines used to treat hepatitis
- Medicines used to treat depression

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving Kadcyla.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Kadcyla.

4. How is Kadcyla given?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.
Kadcyla is prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.

Kadcyla is given by a slow drip into a vein (intravenous (IV) infusion) once every three weeks.

The first infusion will be given over 90 minutes. If the first infusion is well tolerated, your drip time may be shortened to 30 minutes.

You doctor will decide how long you should receive Kadcyla. This will depend on how you respond to treatment and the state of your disease.

If you miss a dose of Kadcyla

As Kadcyla is given under the supervision of your doctor, you are unlikely to miss a dose. However, if you forget or miss your appointment to receive Kadcyla, make another appointment as soon as possible. Do not wait for your next planned appointment. Your doctor will decide when your next dose of Kadcyla will be.

If you are given too much Kadcyla (overdose)

As Kadcyla is given under the supervision of your doctor it is unlikely that you will be given too much. However, if you experience any side effects after being given Kadcyla, tell your doctor or nurse immediately.

5. What should I know while using Kadcyla?

Things you should do

Tell all doctors, dentists and pharmacists who are treating you that you are receiving Kadcyla.

Tell your doctor if you intend to start a family while receiving Kadcyla.

Tell your doctor if you feel that Kadcyla is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor will perform regular tests to monitor for;

- Liver problems
- Heart problems
- Bleeding problems
- Lung problems

Things you should not do

Do not stop your Kadcyla treatment without talking to your doctor first.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Kadcyla affects you.

It is not known whether Kadcyla may affect your ability to drive or operate machinery. If you experience infusion-related reactions, such as flushing, shivering episodes, fever, trouble breathing, low blood pressure or a rapid heartbeat, do not drive and use machines until symptoms abate.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Kadcyla will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C and 8°C. Kadcyla solution should not be frozen.

6. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well while you are receiving Kadcyla.

Kadcyla may have some unwanted side effects in some people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may be more serious and need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
During an 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 • burning sensation or tenderness 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 immediately if you notice any of the following while receiving an infusion (particularly during the first infusion).** These may be serious side effects. You may require urgent medical attention.
After an infusion: • 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, being woken from your sleep or when exercising • chest pain, especially if it worsens with breathing • abdominal pain • increased pain, discoloration, blistering and sloughing of your skin • jaundice (your skin and whites of your eyes look yellow) • dark urine • rash, itching or hives on the skin • loss of appetite	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Less serious side effects

Less serious side effects	What to do
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)	**Speak to your doctor or nurse as soon as possible if you notice any of these.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects tothe Centre for Adverse Reactions Monitoring (CARM) online at

https://nzphvc.otago.ac.nz/consumer-reporting/. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Kadcyla contains

Active ingredient **(main ingredient)**	Each vial of Kadcyla contains 100 mg or 160 mg of the active ingredient, trastuzumab emtansine. The trastuzumab protein is made using Chinese hamster ovary cells.
Other ingredients **(inactive ingredients)**	Succinic acid Sodium hydroxide Sucrose Polysorbate 20

Do not take this medicine if you are allergic to any of these ingredients.

What Kadcyla looks like

Kadcyla is a white to off-white powder which is dissolved in sterile water before use.

After dissolving, the Kadcyla solution should appear as a clear colourless to pale brown solution.

Kadcyla is supplied as a single use vial and is available in two strengths, 100 mg and 160 mg.

Who distributes Kadcyla

Roche Products (NZ) Limited

PO Box 109113 Newmarket

Auckland 1149

NEW ZEALAND

Medical enquiries: 0800 276 243

This leaflet was prepared in October 2025.