New Zealand Consumer Medicine Information

KADCYLA®

Trastuzumab emtansine (rch)

100 mg and 160 mg powder for intravenous infusion

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.

What is in this leaflet

This leaflet answers some common questions about Kadcyla.

It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Kadcyla against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What Kadcyla is used for

Kadcyla contains an active ingredient called 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have given it for another reason.

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

Before you are given Kadcyla

Before you are given it

Tell 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. (Coumadin®, Marevan®)**

  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.
- **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. See "*side effects*" for symptoms to look out for.
- **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.
- **you are breast-feeding or plan to breast-feed**

  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.

Taking other medicines

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

The following medicines may interfere with Kadcyla;

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

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

How Kadcyla is 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

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 (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.

While you are receiving Kadcyla

Things you must do

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

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

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 must not do

Do not stop your Kadcyla treatment without talking to your doctor first.
Tell your doctor if you feel that Kadcyla is not helping your condition.

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

Things to be careful of

Be careful driving or operating machinery 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 fits, fever, trouble breathing, low blood pressure or a rapid heartbeat, do not drive and use machines until symptoms abate.

Side Effects

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

Kadcyla helps most people with HER2 positive 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.

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, being woken from your sleep or when exercising
- chest pain, especially if it worsens with breathing
- 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)

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.

Product description

Storage

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.

Availability

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

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.

Ingredients

Each vial of Kadcyla contains 100 mg or 160 mg of the active ingredient, **trastuzumab emtansine**.
It also contains;

- Succinic acid
- Sodium hydroxide
- Sucrose
- Polysorbate 20

The trastuzumab protein is made using Chinese hamster ovary cells.

Sponsor Details

Kadcyla is supplied in New Zealand by:

Roche Products (New Zealand) Limited
PO Box 109113 Newmarket
Auckland 1149
NEW ZEALAND

Medical enquiries: 0800 656 464

Date of Preparation

This leaflet was prepared on 11 April 2022