PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Kadcyla® 100 mg; powder for concentrate for solution for infusion

Kadcyla® 160 mg; powder for concentrate for solution for infusion

The active substance is trastuzumab emtansine

Contains sugar (sucrose)

Read all of this leaflet carefully before you start using Kadcyla

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.

What is in this leaflet

1. What Kadcyla is and what it is used for

Kadcyla is used to treat early breast cancer (EBC) in adults when:

- The cancer cells have many HER2 proteins on them – your doctor will test your cancer cells for this.
- The cancer has not spread to other parts of your body and treatment is going to be given after surgery (treatment after surgery is called adjuvant therapy).

Kadcyla is used to treat metastatic breast cancer (MBC) in adults when:

- the cancer cells have many HER2 proteins on them - your doctor will test your cancer cells for this.
- you have already received the medicine trastuzumab and a medicine known as a taxane.
- the cancer has spread to areas near the breast or to other parts of your body.

How Kadcyla works

Kadcyla contains the active substance trastuzumab emtansine, which is made up of two parts that are linked together:

- trastuzumab - a monoclonal antibody that binds selectively to HER2 and stops the cancer cells growth and cause them to die.
- DM1 – an anti-cancer substance that stops cancer cells from producing new cells and causes them to die.

2. What you need to know before you are given Kadcyla

You must not be given Kadcyla

- if you are allergic to trastuzumab emtansine or any of the other ingredients of this medicine.
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Talk to your doctor or nurse before you are given Kadcyla if:

- you have ever had a serious infusion-related reaction from using trastuzumab characterised by symptoms such as flushing, chills, fever, shortness of breath, difficulty breathing, rapid heartbeat or a drop in blood pressure.
- you are receiving treatment with blood thinning medicines (e.g. warfarin, heparin).
- you have any history of liver problems. Your doctor will check your blood to test your liver function before and regularly during treatment.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before you are given Kadcyla.

Use in children

Kadcyla is not recommended for anyone under the age of 18 years. This is because there is no information on how well it works in this age group.

Other medicines and Kadcyla

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

In particular, tell your doctor or pharmacist if you are taking:

- any medicines to thin your blood such as warfarin or decrease the ability to form blood clot such as aspirin
- medicines for fungal infections called ketoconazole, itraconazole or voriconazole
- antibiotics for infections called clarithromycin or telithromycin
- medicines for HIV called atazanavir, indinavir, nelfinavir, ritonavir or saquinavir.
- medicine for depression called nefazodone

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before you are given Kadcyla.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Pregnancy

You should not be treated with Kadcyla if you are pregnant because Kadcyla may cause harm to your unborn baby (see “You must not be given Kadcyla”).

- Tell your doctor before using Kadcyla if you are pregnant, think you may be pregnant or are planning to have a baby.

- Use effective contraception to avoid becoming pregnant while you are being treated with Kadcyla. Talk to your doctor about the best contraception for you.
- You should continue to take your contraception for at least 7 months after your last dose of Kadcyla. Talk to your doctor before stopping your contraception.
- Male patients or their female partners should also use effective contraception.
- If you do become pregnant during treatment with Kadcyla, tell your doctor straight away.

Breastfeeding

You should not breastfeed during treatment with Kadcyla. Also you should not breastfeed for 7 months after your last infusion of Kadcyla. It is not known whether the ingredients in Kadcyla pass into breastmilk. Talk to your doctor about this.

Driving and using machines

If you experience flushing, shivering fits, fever, trouble breathing, low blood pressure or a rapid heartbeat (infusion-related reaction), blurred vision, tiredness, headache, confusion or dizziness, do not drive, cycle, use tools or machines until these reactions stop.

Kadcyla contains sucrose and sodium

Kadcyla contains sugar (sucrose) which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Kadcyla.

Kadcyla contains less than 1 mmol (23 mg) per dose. It is essentially “sodium free”.

3. How you are given Kadcyla

Kadcyla will be given to you by a doctor or nurse in a hospital or clinic:

- It is given by a drip into a vein (intravenous infusion).
- You will be given one infusion every 3 weeks.

How much you will be given

- You will be given 3,6 mg of Kadcyla for every kilogram of your body weight. Your doctor will calculate the correct dose for you.
- The first infusion will be given to you over 90 minutes. You will be observed by a doctor or nurse while it is being given and for at least 90 minutes following the initial dose, in case you have any side effects.
- If the first infusion is well tolerated, the infusion on your next visit may be given over 30 minutes. You will be observed by a doctor or nurse while it is being given and for at least 30 minutes following the dose, in case you have any side effects.
- The total number of infusions that you will be given depends on how you respond to the treatment and which indication is treated.

If you experience side effects, your doctor may decide to continue your treatment but lower your dose, delay the next dose or stop the treatment.

If you miss a Kadcyla treatment

If you forget or miss your Kadcyla appointment, make another appointment as soon as possible. Do not wait until your next planned visit.

If you stop Kadcyla treatment

Do not stop treatment with this medicine without talking to your doctor first. If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Kadcyla can have side effects.

Not all side effects reported for Kadcyla are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Breathing problems

Kadcyla can cause serious breathing problems such as

- shortness of breath (either at rest or while performing any type of activity) and
- cough.

If you develop these symptoms your doctor may stop treatment with this medicine.

Heart problems

Kadcyla can weaken the heart muscle. When the heart muscle is weak, you may develop symptoms such as

- shortness of breath at rest or when sleeping,
- chest pain,
- swollen legs or arms, and
- a sensation of rapid or irregular heartbeats.

Your doctor will check your heart function before and regularly during treatment.

Infusion-related reactions or allergic reactions

Kadcyla can cause

- flushing,
- shivering fits,
- fever,
- trouble breathing,

- low blood pressure,
- rapid heartbeat,
- sudden swelling of your face, tongue, or trouble swallowing during the infusion or after the infusion on the first day of treatment.

Bleeding problems

Kadcyla can lower the number of platelets in your blood. Platelets help your blood to clot so you might get unexpected bruising or bleeding (such as nose bleeds, bleeding from gums). Your doctor will check your blood regularly for decreased platelets. You should tell your doctor immediately if you notice any unexpected bruising or bleeding.

Neurological problems

Kadcyla can damage nerves. You may experience

- tingling,
- pain,
- numbness,
- itching,
- crawling sensation,
- pins and needles in your hands and feet.

Your doctor will monitor you for signs and symptoms of neurological problems.

Liver problems

Kadcyla can cause inflammation or damage to cells in the liver that can stop the liver from functioning normally. Inflamed or injured liver cells may leak higher than normal amounts of certain substances (liver enzymes) unto the blood stream, resulting in elevated liver enzymes in blood tests. In most cases you will not have any symptoms. Some symptoms could be yellowing of your skin and whites

of your eyes (jaundice). Your doctor will check your blood to test your liver function before and regularly during treatment.

These are all serious side effects. You may need urgent medical attention.

Other side effects include

Frequent:

- decreased red blood cells (shown in a blood test)
- being sick (vomiting)
- diarrhoea
- dry mouth
- urinary tract infection
- constipation
- stomach ache
- cough
- shortness of breath
- inflammation of the mouth
- chills or flu like symptoms
- decrease in your potassium levels (shown in a blood test)
- difficulty sleeping
- muscle or joint pain
- fever
- headache
- skin rashes
- feeling tired
- weakness
- decreased white blood cells (shown in a blood test)
- dry eyes, watery eyes or blurred vision
- eye redness or infection

- indigestion
- swelling of legs and/or arms
- bleeding from the gums
- increase in blood pressure
- feeling dizzy
- taste disturbances
- itching
- difficulty in remembering
- hair loss
- hand-and-foot skin reaction (Palmar-plantar erythrodysaesthesia syndrome)
- nail disorder

Less frequent:

Another abnormality that can be caused by Kadcyla is a condition known as nodular regenerative hyperplasia (NRH) of the liver. This abnormality causes the structure of the liver to change. Patients develop multiple nodules in the liver that can change how the liver functions. Over time, this may lead to symptoms such as a bloated sensation or swelling of the abdomen due to fluid accumulation or bleeding from abnormal blood vessels in the gullet or rectum.

If the Kadcyla infusion solution leaks into the area around the infusion site you may develop tenderness or redness of your skin, or swelling at the infusion site.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Kadcyla.

5. How to store Kadcyla

Kadcyla will be stored by the health professionals at the hospital or clinic.

- Store all medicines out of reach of children.
- Do not use this medicine after the expiry date which is stated on the outer carton after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator at (2 - 8 °C). Do not freeze.
- When prepared as a solution for infusion Kadcyla is stable for up to 24 hours at 2°C to 8°C, and must be discarded thereafter.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Kadcyla contains

The active substance is trastuzumab emtansine.

- Each 100 mg single-use vial containing powder for concentrate for infusion solution designed to deliver 5 mL of 20 mg/mL of trastuzumab emtansine.
- Each 160 mg single-use vial containing powder for concentrate for infusion solution designed to deliver 8 mL of 20 mg/mL of trastuzumab emtansine.
- The other ingredients are polysorbate 20, sodium hydroxide, succinic acid and sucrose.

What Kadcyla looks like and contents of the pack

Kadcyla is a white to off-white lyophilised powder supplied in glass vials.

Kadcyla 100: Pack of 1 vial. Colourless 15 mL Type 1 glass vial closed with a fluoro-resin laminated grey butyl rubber stopper, sealed with an aluminium seal and a white plastic flip-off cap.

Kadcyla 160: Pack of 1 vial. Colourless 20 mL Type 1 glass vial closed with a fluoro-resin laminated grey butyl rubber stopper, sealed with an aluminium seal and a purple plastic flip-off cap.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Roche Products (Pty) Ltd

90 Bekker Road, Hertford Office Park,

Building E, Vorna Valley, Midrand,

Johannesburg, 1686

South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

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