PRODUCT MONOGRAPH

PrKADCYLA®

trastuzumab emtansine for injection

100 mg and 160 mg vial

For intravenous infusion only

Sterile powder for concentrate for infusion solution

Antibody-drug conjugate

Antineoplastic

Hoffmann-La Roche Limited
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Mississauga, Ontario, Canada
L5N 5M8

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PART III: CONSUMER INFORMATION

PrKADCYLA®
trastuzumab emtansine for injection

This leaflet is part III of a three-part "Product Monograph" published when KADCYLA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about KADCYLA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
KADCYLA pronounced "Kad-s(eye)-la" is used to treat people with breast cancer when:

- the cancer cells produce a large amount of HER2 proteins - your healthcare provider will test your cancer for this
- you have already received the medicine HERCEPTIN (trastuzumab) separately or in combination with a chemotherapy medicine from the class called taxane e.g. paclitaxel or docetaxel
- the cancer has spread to areas near the breast or to other parts of your body

What it does:
KADCYLA is made up of two types of medicine that are linked together. One part belongs to a group of medicines called monoclonal antibodies (HERCEPTIN) and the other belongs to a group of medicines called anti-mitotics (DM1).

KADCYLA recognizes the cancer cells in the body by attaching to HER2 proteins. When KADCYLA attaches to the HER2 cancer cells, it may slow or stop the growth of the cancer or may also kill the cancer cells. After KADCYLA attached to HER2 proteins, it enters the cancer cells where it releases the anti-mitotic drug DM1. DM1 may also kill the cancer cells.

When it should not be used:
You should not be given KADCYLA if you are allergic to this drug or to any ingredients in the formulation (see 'What the medicinal ingredient is' and 'What the important non-medicinal ingredients are'). If you are not sure, talk to your healthcare provider before you are given KADCYLA.

What the medicinal ingredient is:
KADCYLA contains the active substance trastuzumab emtansine which is made up of two medicinal ingredients that are linked together:

- trastuzumab
- DM1

What the important non-medicinal ingredients are:
The non-medicinal ingredients are (alphabetical order); polysorbate 20, sodium hydroxide, succinic acid, and sucrose.

What dosage forms it comes in:
KADCYLA is a sterile, white to off-white powder that will be reconstituted and given as an intravenous (IV) administration. It is supplied in a single-use vial containing either 100 mg or 160 mg of trastuzumab emtansine.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Medication Errors: There is a risk of KADCYLA overdose due to medication errors. Verify with the healthcare provider that the authorized KADCYLA (trastuzumab emtansine) dose and NOT HERCEPTIN (trastuzumab) dose is used.

Liver Problems: KADCYLA can cause inflammation and damage to liver cells. Severe liver damage may result in liver failure and death. To monitor liver problems, your blood will be checked regularly for increases in levels of liver enzymes.

Heart Problems: KADCYLA can weaken the heart muscle leading to problems pumping the blood around your body and causing shortness of breath at rest, chest pain, swollen ankles or arms, and a sensation of rapid or irregular heartbeats. Your heart function will be checked before and regularly during treatment.

Bleeding Problems: Platelets in the blood help blood clot. KADCYLA can lower the number of platelets in your blood and cause life-threatening bleeding. In some cases, bleeding has been fatal. The risk of bleeding is increased when taking KADCYLA with other medications used to thin your blood or prevent blood clots. Your doctor should provide additional monitoring if you are taking one of these other drugs.

Lung problems: KADCYLA may cause lung problems, including inflammation (swelling) of the lung tissue, leading to lung failure and death.

Embryo-fetal toxicity (Harm to Unborn Baby): KADCYLA can cause harm to the fetus (unborn baby), or death of the fetus, when taken by a pregnant woman. Women who could become pregnant need to use two effective birth control methods during KADCYLA treatment and for at least 7 months after treatment with KADCYLA.

BEFORE you use KADCYLA talk to your doctor or pharmacist if:

- you have ever had a serious infusion-related (allergic) reaction when treated with trastuzumab
- you are receiving treatment with blood thinner medications
- you have any history of liver problems. Your doctor will check your blood to test your liver function before and regularly during treatment.

KADCYLA can make some existing conditions worse, or cause side effects. See 'Side Effects and What to Do About Them' below.

Patients aged below 18 years, and Patients aged 75 years or above: KADCYLA should not be used in these patients as there is no information on how it works in these age groups.

Pregnancy, breast-feeding and fertility: KADCYLA is not recommended if you are pregnant. There is no information about the safety of KADCYLA in pregnant women. KADCYLA may affect fertility based on animal studies.

- 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. Also use this contraception for 7 months after your last dose. Female partners of male patients should also use effective contraception. Talk to your healthcare provider about the best contraception for you.
- If you do become pregnant during treatment with KADCYLA, tell your healthcare provider straight away.

Do not breast-feed during treatment with KADCYLA and for 7 months after stopping treatment. It is not known whether the ingredients in KADCYLA pass into breast-milk. Talk to your doctor about this.

Driving and using machines: It is not known whether KADCYLA affects your ability to drive or use machines. If you experience infusion-related reactions (e.g. flushing, shivering fits, fever, trouble breathing, low blood pressure, rapid heartbeat, sudden swelling of your face, tongue, or trouble swallowing) do not drive and use machines until symptoms abate completely.

INTERACTIONS WITH THIS MEDICATION

Tell your healthcare provider if you are taking, have recently taken or might take any other medicines.

This includes medicines obtained without a prescription and herbal medicines. In particular, tell your healthcare provider if you are taking blood thinners.

PROPER USE OF THIS MEDICATION

Usual dose:
KADCYLA will be given to you by a healthcare provider in a hospital or clinic:

- It is given by a drip into a vein (intravenous infusion) once every 3 weeks at a dose of 3.6 mg of KADCYLA for every kilogram of your body weight.
- The first infusion will be given to you over 90 minutes. You will be watched by a healthcare provider 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 watched by a healthcare provider 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.
- If you experience side effects, your doctor may decide to carry on your treatment but lower your dose, delay the next dose or stop the treatment.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately even if there are no symptoms.

There is a risk of KADCYLA overdose due to medication errors. Verify with the healthcare provider that the authorized KADCYLA (trastuzumab emtansine) dose and NOT HERCEPTIN (trastuzumab) dose is used.

Missed Dose:
If you forget or miss your KADCYLA appointment, discuss this as soon as possible with your healthcare provider to make another appointment.

Do not stop having this medicine without talking to your healthcare provider first. If you have any further questions on the use of this medicine, ask your healthcare provider.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, this medicine can cause unwanted effects. Tell your health care provider if you notice any of the side effects given below.

Very common (may affect more than 1 in 10 people):

- Jaundice
- Unexpected bleeding
- Tiredness,
- Feeling sick (nausea, vomiting)
- Headache
- Muscle or joint pain
- Abdominal pain
- Constipation
- Nerve damage
- Diarrhea
- Dry mouth
- Swelling of the mouth
- Chills or flu like symptoms
- Difficulty sleeping
- Decrease in your potassium levels (shown in a blood test)
- Decreased red blood cells (shown in a blood test)

Common (may affect up to 1 in 10 people):

- Heart problems
- Infusion-related reactions/Hypersensitivity (Allergic reaction): Decreased white blood cells (shown in a blood test)

- Swollen mouth or eyelids
- Dry eyes, watery eyes or blurred vision
- Increase in blood pressure
- Dizziness
- Loss of taste
- Itching

Uncommon (may affect up to 1 in 100 people):
- Breathing problems
- KADCYLA can cause a condition known as nodular regenerative hyperplasia of the liver. 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 you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet.

If you get any of the side effects after your treatment with KADCYLA has been stopped, talk to your doctor and tell them that you have been treated with KADCYLA.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your healthcare provider immediately		Stop taking drug and call your healthcare provider
		Only if severe	In all cases	
Very Common	Unexpected bleeding from the nose, gums	✓		
	your skin and whites of your eyes get yellow		✓	
Common	Shortness of breath at rest, chest pain, swollen ankles or arms, sensation of rapid or irregular heartbeats		✓	
	Tenderness or redness of your skin, or swelling at the injection site.		✓	
	Flushing, shivering fits, fever, trouble breathing, low blood pressure, rapid heartbeat, sudden swelling of your face, tongue, trouble swallowing		✓	
	Tingling, pain, numbness, itching, crawling sensation, pins and needles in your hands and feet	✓		
Uncommon	Shortness of breath, cough with fever		✓	
	Blood in stools, swelling of the abdomen	✓		
If you become pregnant			✓	

This is not a complete list of side effects. For any unexpected effects while taking KADCYLA, contact your doctor or pharmacist.

HOW TO STORE IT

- KADCYLA will be stored by the healthcare professionals at the hospital or clinic.
- Keep this medicine out of the sight and 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 vials in a refrigerator at (2-8°C).

When prepared, as a solution for infusion KADCYLA is stable for up to 24 hours at 2-8°C, and must be discarded thereafter. Do not use KADCYLA if you notice any particles or it is the wrong colour see 'What dosage forms it comes in'.

- 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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to:**

    Canada Vigilance Program
    Health Canada
    Postal Locator 1908C
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more detailed information, please also see Part I: WARNINGS AND PRECAUTIONS of the KADCYLA product monograph. The product monograph is a document prepared for healthcare professionals and can be found at:
www.rochecanada.com
or by contacting the sponsor, Hoffmann-La Roche Limited, at:
1-888-762-4388.

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