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EPAR summary for the public

Kadcyla

trastuzumab emtansine

This is a summary of the European public assessment report (EPAR) for Kadcyla. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Kadcyla.

For practical information about using Kadcyla, patients should read the package leaflet or contact their doctor or pharmacist.

What is Kadcyla and what is it used for?

Kadcyla is a cancer medicine that contains the active substance trastuzumab emtansine. It is used to treat advanced or metastatic breast cancer (cancer that has spread to other parts of the body) in adults who previously received trastuzumab and a taxane (type of cancer medicine).

Kadcyla can only be used when the cancer has been shown to 'overexpress HER2': this means that the cancer cell produces on its surface large quantities of a protein which stimulates the growth of the cancer cell and is called HER2 (human epidermal growth factor).

How is Kadcyla used?

Kadcyla can only be obtained with a prescription and treatment should be prescribed by a doctor and given under the supervision of a healthcare professional who is experienced in the treatment of cancer patients.

Kadcyla is available as a powder that is made up into a solution for infusion (drip) into a vein. The dose to be given depends on the patient's bodyweight and the infusion is repeated every 3 weeks. Patients who tolerate the first 90-minute infusion can receive subsequent infusions over 30 minutes. Patients may remain on treatment unless the disease gets worse or unless they no longer tolerate treatment.

Patients should be observed during and after the infusion for any infusion-related reactions such as flushing, shivering fits and fever. In patients who develop allergic reactions or side effects, the treating doctor may have to reduce the dose or stop treatment with Kadcyla.

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For further information, see the package leaflet.

How does Kadcyla work?

The active substance in Kadcyla, trastuzumab emtansine, is made up of two active components which are linked together:

- Trastuzumab, a monoclonal antibody (a type of protein) that has been designed to recognise and attach to the protein HER2, which is found in large quantities on the surface of some cancer cells. By attaching to HER2, trastuzumab activates cells of the immune system, which then kill the cancer cells. Trastuzumab also stops HER2 from stimulating the growth of the cancer cells. About a quarter of breast cancers overexpress HER2.
- DM1, a toxic substance that kills cells when they attempt to divide and grow. DM1 becomes active once Kadcyla enters the cancer cell. It attaches to a protein in cells called 'tubulin', which is important in the formation of the internal 'skeleton' that cells need to assemble when they divide. By attaching to tubulin in cancer cells, DM1 stops the formation of this skeleton, preventing the division and growth of the cancer cells.

What benefits of Kadcyla have been shown in studies?

Kadcyla has been shown to significantly delay disease getting worse and to prolong survival in patients with advanced and metastatic breast cancer that expressed HER2 and who were previously treated with trastuzumab and a taxane. In one main study, which involved 991 such patients, those treated with Kadcyla lived on average for 9.6 months without their disease getting worse compared with 6.4 months for patients who were treated with two other anti-cancer medicines, capecitabine and lapatanib. Patients treated with Kadcyla also survived for 31 months compared with 25 months for patients treated with capecitabine and lapatinib.

What are the risks associated with Kadcyla?

The most common side effects with Kadcyla (which may affect more than 25% of patients) are nausea (feeling sick), fatigue (tiredness) and headache. The most common serious side effects are haemorrhage (bleeding), pyrexia (fever), dyspnoea (difficulty breathing), musculoskeletal pain (pain in muscles and bones), thrombocytopenia (low blood platelet counts), abdominal pain (stomach ache), and vomiting.

For the full list of all side effects reported with Kadcyla, see the package leaflet.

Why is Kadcyla approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Kadcyla's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that in patients treated with Kadcyla, there was a significant improvement in survival compared with standard therapy. Regarding Kadcyla's safety, overall side effects were considered to be manageable and the overall safety profile was considered favorable compared with other currently available medicines.

What measures are being taken to ensure the safe and effective use of Kadcyla?

A risk management plan has been developed to ensure that Kadcyla is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Kadcyla, including the appropriate precautions to be followed by healthcare professionals and patients.

Because of a potential risk of confusion between Kadcyla and Herceptin due to their similar sounding active substances (trastuzumab emtansine and trastuzumab) the company will provide educational material to all healthcare professionals expected to use Kadcyla or Herceptin to alert them not to use these medicines interchangeably and to inform them of measures they should take to avoid medication errors.

Other information about Kadcyla

The European Commission granted a marketing authorisation valid throughout the European Union for Kadcyla on 15.11.2013.

The full EPAR for Kadcyla can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Kadcyla, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2016.