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Capecitabine medac (*capecitabine*)

An overview of Capecitabine medac and why it is authorised in the EU

What is Capecitabine medac and what is it used for?

Capecitabine medac is a cancer medicine that is used to treat:

- colon (large bowel) cancer. Capecitabine medac is used on its own or with other cancer medicines in patients who have had surgery for stage III or Dukes' stage C colon cancer;
- metastatic colorectal cancer (cancer of the large bowel that has spread to other parts of the body). Capecitabine medac is used on its own or with other cancer medicines;
- advanced gastric (stomach) cancer. Capecitabine medac is used with other cancer medicines, including a platinum-containing cancer medicine such as cisplatin;
- locally advanced or metastatic breast cancer (breast cancer that has begun to spread to other parts of the body). Capecitabine medac is used with docetaxel (another cancer medicine) after treatment with anthracyclines (another type of cancer medicine) has failed. It can also be used on its own when treatment with both anthracyclines and taxanes (another type of cancer medicine) has failed or when further treatment with anthracyclines is not suitable for the patient.

Capecitabine medac is a 'generic' and a 'hybrid' medicine. This means that it is similar to a 'reference medicine', but it contains capecitabine at a new strength in addition to existing strengths. While the reference medicine, Xeloda, is available as 150 and 500 mg tablets, Capecitabine medac is also available as 300 mg tablets. For more information on generic and hybrid medicines, see the question-and-answer document here.

Capecitabine medac contains the active substance capecitabine.

How is Capecitabine medac used?

Capecitabine medac should only be prescribed by a doctor who is qualified in the use of cancer medicines.

Before starting treatment, it is recommended that patients are tested to check that they have a working dihydropyrimidine dehydrogenase (DPD) enzyme.

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Capecitabine medac is available as tablets (150, 300 and 500 mg). The dose depends on the patient's height and weight and the type of cancer being treated. Capecitabine medac tablets should be taken within 30 minutes after a meal. The tablets are given twice daily for 14 days followed by a 7-day gap before the next course.

Treatment is continued for six months after colon surgery. For other types of cancer, treatment is stopped if the disease gets worse or the side effects are unacceptable. Doses need to be adjusted for patients with liver or kidney disease and for patients who develop certain side effects. For patients with partial DPD deficiency, a lower starting dose may be considered.

For more information about using Capecitabine medac, see the package leaflet or contact your doctor or pharmacist.

How does Capecitabine medac work?

The active substance in Capecitabine medac, capecitabine, is a cytotoxic medicine (a medicine that kills rapidly dividing cells, such as cancer cells) that belongs to the group 'anti-metabolites'. Capecitabine is converted to the medicine fluorouracil in the body, but more is converted in tumour cells than in normal tissues.

Fluorouracil is very similar to pyrimidine. Pyrimidine is part of the genetic material of cells (DNA and RNA). In the body, fluorouracil takes the place of pyrimidine and interferes with the enzymes involved in making new DNA. As a result, it stops the growth of tumour cells and eventually kills them.

How has Capecitabine medac been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Xeloda, and do not need to be repeated for Capecitabine medac.

As for every medicine, the company provided studies on the quality of Capecitabine medac. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Capecitabine medac?

Because Capecitabine medac is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Capecitabine medac authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Capecitabine medac has been shown to have comparable quality and to be bioequivalent to Xeloda. Therefore, the Agency's view was that, as for Xeloda, the benefits of Capecitabine medac outweigh the identified risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Capecitabine medac have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Capecitabine medac are continuously monitored. Side effects reported with Capecitabine medac are carefully evaluated and any necessary action taken to protect patients.

Other information about Capecitabine medac

Capecitabine medac received a marketing authorisation valid throughout the European Union on 19 November 2012.

Further information on Capecitabine medac can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/capecitabine-medac

Information on the reference medicine can also be found on the Agency's website.

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