EMA/373912/2020
EMEA/H/C/002362

Capecitabine Teva (*capecitabine*)

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

What is Capecitabine Teva and what is it used for?

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

- colon (large bowel) cancer. Capecitabine Teva 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 Teva is used on its own or with other cancer medicines;
- advanced gastric (stomach) cancer. Capecitabine Teva 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 Teva 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 Teva is a 'generic medicine'. This means that Capecitabine Teva contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Xeloda. For more information on generic medicines, see the question-and-answer document here.

Capecitabine Teva contains the active substance capecitabine.

How is Capecitabine Teva used?

Capecitabine Teva 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.

Capecitabine Teva is available as tablets (150 and 500 mg). The dose depends on the patient's height and weight and the type of cancer being treated. Capecitabine Teva 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 Teva, see the package leaflet or contact your doctor or pharmacist.

How does Capecitabine Teva work?

The active substance in Capecitabine Teva, 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 an analogue of 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 inhibits the growth of tumour cells and eventually kills them.

How has Capecitabine Teva 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 Teva.

As for every medicine, the company provided studies on the quality of Capecitabine Teva. 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 Teva?

Because Capecitabine Teva 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 Teva authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Capecitabine Teva 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 outweighs 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 Teva?

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

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

Other information about Capecitabine Teva

The European Commission granted a marketing authorisation valid throughout the European Union for Capecitabine Teva on 20 April 2012.

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

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

This overview was last updated in 06-2020.