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EPAR summary for the public

Capecitabine SUN

capecitabine

This is a summary of the European public assessment report (EPAR) for Capecitabine SUN. 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 Capecitabine SUN.

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

What is Capecitabine SUN and what is it used for?

Capecitabine SUN is an anticancer medicine that contains the active substance capecitabine. It is used to treat:

- colon (large bowel) cancer. Capecitabine SUN is used with or without other anticancer 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 SUN is used with or without other anticancer medicines;
- advanced gastric (stomach) cancer. Capecitabine SUN is used with other anticancer medicines, including a platinum-containing anticancer medicine such as cisplatin;
- locally advanced or metastatic breast cancer (breast cancer that has begun to spread to other parts of the body). Capecitabine SUN is used with docetaxel (another anticancer medicine) after treatment with anthracyclines (another type of anticancer medicine) has failed. It can also be used on its own when treatment with both anthracyclines and taxanes (another type of anticancer medicine) has failed or when repeat treatment with anthracyclines is not suitable for the patient.

Capecitabine SUN is a 'generic medicine'. This means that Capecitabine SUN is similar to a 'reference medicine' already authorised in the European Union (EU) called Xeloda. For more information on generic medicines, see the question-and-answer document here.

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How is Capecitabine SUN used?

Capecitabine SUN is available as tablets (150 and 500 mg). It can only be obtained with a prescription and must be prescribed by a doctor who is experienced in the use of anticancer medicines.

Capecitabine SUN is taken twice a day at doses between 625 and 1,250 mg per square metre body surface area (calculated using the patient's height and weight). The dose depends on the type of cancer being treated. The doctor will calculate the number of 150- and 500-mg tablets the patient needs to take. Capecitabine SUN tablets should be swallowed with water within the 30 minutes after a meal.

Treatment is continued for six months after colon surgery. For other types of cancer, treatment is stopped if the disease gets worse or the patient cannot tolerate the treatment. Doses need to be adjusted for patients with liver or kidney disease and for patients who develop certain side effects.

Full details are available in the summary of product characteristics (also part of the EPAR).

How does Capecitabine SUN work?

The active substance in Capecitabine SUN, capecitabine, is a cytotoxic medicine (a medicine that kills cells that are dividing, such as cancer cells) that belongs to the group 'anti-metabolites'. Capecitabine is a 'prodrug' that is converted to 5-fluorouracil (5-FU) in the body, mainly in tumour cells. It is taken as tablets, while 5-FU normally needs to be injected.

5-FU is an analogue of pyrimidine. Pyrimidine is part of the genetic material of cells (DNA and RNA). In the body, 5-FU takes the place of pyrimidine and interferes with the enzymes involved in making new DNA. As a result, it blocks the growth of tumour cells and eventually kills them.

How has Capecitabine SUN been studied?

Because Capecitabine SUN is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Xeloda. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Capecitabine SUN?

Because Capecitabine SUN 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 has Capecitabine SUN been approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Capecitabine SUN has been shown to have comparable quality and to be bioequivalent to Xeloda. Therefore, the CHMP's view was that, as for Xeloda, the benefit outweighs the identified risk. The Committee recommended that Capecitabine SUN be approved for use in the EU.

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

A risk management plan has been developed to ensure that Capecitabine SUN 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 Capecitabine SUN, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Capecitabine SUN

The European Commission granted a marketing authorisation valid throughout the European Union for Capecitabine SUN on 21 June 2013.

The full EPAR for Capecitabine SUN 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 Capecitabine SUN, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 06-2013.