LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Capecitabine Pharmagen (capecitabine)

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Summary Public Assessment Report

Capecitabine Pharmagen
(capecitabine)

Film-coated tablets 150 and 500 mg

This is a summary of the public assessment report (PAR) for Capecitabine Pharmagen. It explains how Capecitabine Pharmagen was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Capecitabine Pharmagen.

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

What is Capecitabine Pharmagen and what is it used for?

Capecitabine Pharmagen is a 'generic medicine'. This means that Capecitabine Pharmagen is similar to a 'reference medicine' already authorised in the European Union (EU) called Xeloda.

Capecitabine Pharmagen is used in the treatment of colon, rectal, gastric, or breast cancers. Furthermore, Capecitabine Pharmagen is used to prevent new occurrence of colon cancer after complete removal of the tumour by surgery.

Capecitabine Pharmagen may be used either alone or in combination with other medicines.

How does Capecitabine Pharmagen work?

Capecitabine Pharmagen belongs to the group of medicines called "cytostatic medicines", which stop the growth of cancer cells. Capecitabine Pharmagen contains capecitabine, which itself is not a cytostatic medicine. Only after being absorbed by the body is it changed into an active anti-cancer medicine (more in tumour tissue than in normal tissue).

How is Capecitabine Pharmagen used?

The pharmaceutical form of Capecitabine Pharmagen is film-coated tablets for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Capecitabine Pharmagen have been shown in studies?

Because Capecitabine Pharmagen 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 possible side effects of Capecitabine Pharmagen?

Because Capecitabine Pharmagen is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Capecitabine Pharmagen approved?

It was concluded that, in accordance with EU requirements, Capecitabine Pharmagen has been shown to have comparable quality and to be bioequivalent to the reference medicine Xeloda. Therefore, the Medical Products Agency in Sweden decided that, as for Xeloda, the benefits are greater than its risks and recommended that it can be approved for use.

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

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

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Capecitabine Pharmagen

The marketing authorisation for Capecitabine Pharmagen was granted on 2012-10-04 in Sweden.

The full PAR for Capecitabine Pharmagen can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Capecitabine Pharmagen, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2014-12.