LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Cantaloda
(capecitabine)

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Summary Public Assessment Report

Cantaloda
(capecitabine)

Film-coated tablets 150 and 500 mg

This is a summary of the public assessment report (PAR) for Cantaloda. It explains how Cantaloda 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 Cantaloda.

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

What is Cantaloda and what is it used for?

Cantaloda is a ‘generic medicine’. This means that Cantaloda is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Xeloda.

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

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

How does Cantaloda work?

Cantaloda belongs to the group of medicines called "cytostatic medicines", which stop the growth of cancer cells. Cantaloda 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 Cantaloda used?

The pharmaceutical form of Cantaloda 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 Cantaloda have been shown in studies?

Because Cantaloda 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 Cantaloda?

Because Cantaloda 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 Cantaloda approved?

It was concluded that, in accordance with EU requirements, Cantaloda 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 Cantaloda?

A risk management plan has been developed to ensure that Cantaloda 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 Cantaloda, 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 Cantaloda

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

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

This summary was last updated in 2015-03.