20 September 2012
EMA/CHMP/502040/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Capecitabine Medac

capecitabine

On 20 September 2012 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Capecitabine Medac 150 mg, 300 mg, 500 mg film coated tablet intended for the treatment of colon, colorectal, gastric and breast cancer. The applicant for this medicinal product is medac Gesellschaft für klinische Spezialpräparate mbH.

They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Capecitabine Medac is capecitabine, an antineoplastic agent and more specifically an antimetabolite/pyrimidine analogue (L01BC06) which is an orally administered precursor of the well-known cytotoxic moiety 5-fluorouracil (5-FU).

Capecitabine Medac 150 mg, 300 mg, 500 mg film coated tablet is a generic of Xeloda, which has been authorised in the EU since 02 February 2001. Studies have demonstrated the satisfactory quality of Capecitabine Medac 150 mg, 300 mg and 500 mg film coated tablet and its bioequivalence with the reference product Xeloda. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Capecitabine Medac 150 mg, 300 mg and 500 mg film coated tablet will be implemented as part of the marketing authorisation.

The approved indication is:

“Capecitabine is indicated for the adjuvant treatment of patients following surgery of stage III (Dukes’ stage C) colon cancer.

Capecitabine is indicated for the treatment of metastatic colorectal cancer.

Capecitabine is indicated for first-line treatment of advanced gastric cancer in combination with a platinum based regimen.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Capecitabine in combination with docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. Capecitabine Medac is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of taxanes and an anthracycline containing chemotherapy regimen or for whom further anthracycline therapy is not indicated".

It is proposed that Capecitabine Medac be prescribed by qualified physicians experienced in the utilisation of antineoplastic agents.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Capecitabine Medac and therefore recommends the granting of the marketing authorisation.