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Public statement

Capecitabine SUN

Withdrawal of the marketing authorisation in the European Union

On 21 June 2016, the European Commission withdrew the marketing authorisation for Capecitabine SUN (capecitabine) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Sun Pharmaceutical Industries Europe, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Capecitabine SUN was granted marketing authorisation in the EU on 21 June 2013 for the following indications:

- adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer. Capecitabine is indicated for the treatment of metastatic colorectal cancer.

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

- in combination with docetaxel 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 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.

The marketing authorisation was initially valid for a 5-year period.

Capecitabine SUN is a generic medicine of Xeloda. There are other generic medicinal products of Xeloda authorised and marketed in the EU

The European Public Assessment Report (EPAR) for Capecitabine SUN will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.