

Backgrounder

(For Non-US Journalists Only)



XELODA® (CAPECITABINE): THE FACTS

Xeloda: Intelligence, Freedom and Flexibility

BENEFITS OF XELODA

- Xeloda is the first oral chemotherapy drug that produces superior tumour response rates, equivalent progression-free survival, equivalent overall survival rates and a more favourable side effect profile compared with the current standard treatment, intravenous 5-fluorouracil/leucovorin (i.v. 5-FU/LV)
- As Xeloda is an oral tablet, it can be conveniently taken in the comfort of a patient's home, saving them time from hospital visits and sparing them from the discomfort of i.v. treatment- Xeloda allows patients to spend more valuable time with friends and family; offering the freedom to carry on their lives as normal as possible
- By reducing hospital visits, the time spent receiving treatment and lowering treatment related costs of side-effects, Xeloda saves healthcare systems a considerable amount of money:
 - Xeloda can save up to £22 million per year for the UK National Health Service¹
 - With Xeloda, cancer patients experience less severe side effects associated with i.v. chemotherapy, such as hair loss, nausea, diarrhoea, fatigue and vomiting
 - Patients receiving Xeloda do not require surgery to implant i.v. devices, which reduces the risk of infections (and subsequent hospitalisation) from open wounds
 - Xeloda is a 'dominant' treatment option for colon cancer patients as it is a replacement
 - for i.v. 5-FU/LV, based on its efficacy, favourable side-effect profile and economic savings
 - benefit²

HOW DOES XELODA WORK?

- Xeloda is a highly effective and innovative oral chemotherapy drug that targets the cancer-killing agent 5-FU directly at the site of cancer cells without the inconvenience and burden of traditional i.v. therapy
- Xeloda is taken twice a day after food; no fasting is required. This simple treatment schedule provides ongoing chemotherapy cover that mimics the continuous infusion of i.v. 5-FU/LV
- Xeloda has a unique 3-step activation mechanism
 - Xeloda is inactive when it is swallowed, and is absorbed through the gut into the bloodstream
 - The first two steps of the activation process take place in the liver, where Xeloda begins to be converted into a different, non-toxic intermediate
 - The final step of activation takes place in the cancer cells themselves where Xeloda is activated to 5-FU by an enzyme, found at higher levels in cancer cells than in healthy cells. Due to this “tumour-activated” mechanism more of the cancer-killing agent 5-FU is produced where it is needed, in cancer cells, rather than in healthy cells
- Xeloda then kills cancer cells via the 5-FU, which attacks their DNA^{3,4}

XELODA IN COMBINATION THERAPY

- Xeloda promises to be a safe and effective partner for patients with colorectal cancer, in combination with other current treatments such as irinotecan and oxaliplatin:
- In combination with oxaliplatin or irinotecan (given via an i.v. line but on an outpatient
- basis), Xeloda has shown excellent efficacy
- Xeloda in combination with docetaxel is successful in the fight against breast cancer in women
- whose disease has spread to other parts of the body
- For the first time, Xeloda has been proven to be safe and effective in gastric cancer, in combination with cisplatin

INDICATIONS AND LICENSING STATUS

Xeloda is licensed in more than 90 countries worldwide including the EU, USA, Japan, Australia and Canada

COLORECTAL

- Roche received marketing authorisation for Xeloda as a first-line monotherapy (by itself) in the treatment of metastatic colorectal cancer (colorectal cancer that has spread to other parts of the body) in most countries (including the EU and USA) in 2001
- Xeloda has been approved by the European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) for adjuvant (post surgery) treatment of colon cancer in March and June 2005, respectively

BREAST

- Xeloda is licensed in combination with Taxotere® (docetaxel) in women with metastatic breast cancer (breast cancer that has spread to other parts of the body) and whose disease has progressed following intravenous (i.v.) chemotherapy with anthracyclines
- Xeloda monotherapy (by itself) is also indicated for treatment of patients with metastatic breast cancer (breast cancer that has spread to other parts of the body) that is resistant to other chemotherapy drugs such as paclitaxel and anthracyclines

OTHER

- Xeloda is licensed for the first-line treatment of stomach cancer that has spread, in South Korea.

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References

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2. Douillard JY *et al.* Pharmacoeconomic analysis of Capecitabine in the adjuvant setting. Results from the X-ACT trial comparing capecitabine with 5-FU/LV in patients with Dukes' C colon cancer. *Ann Oncol* 2004;15 Sup. 3
3. Maroun JA. Capecitabine in the management of colorectal cancer. *Expert Rev Anticancer Ther* 2001; 1(3): 327 – 333
4. Cunningham D, James RD. Integrating the oral fluoropyrimidines into the management of advanced colorectal cancer. *Eur J Cancer* 2001; 37: 826 – 834