

relapse within six months of completing treatment with an anthracycline-containing adjuvant regimen.

***Xeloda is covered by Medicare.***

To further improve patient safety, Roche submitted data from a clinical trial that confirmed an interaction between Xeloda and warfarin. To heighten physicians' awareness, Roche has agreed with the FDA to make the Xeloda and warfarin interaction information in a black box warning statement and support an ongoing program for physician and patient awareness of the potential interaction between Xeloda and coumarin derivative anticoagulants, such as warfarin.

**XELODA SAFETY INFORMATION**

Patients receiving concomitant capecitabine and oral coumarin-derivative anticoagulant therapy should have their anticoagulant response (INR or prothrombin time) monitored frequently in order to adjust the anticoagulant dose accordingly. A clinically important drug interaction between XELODA and warfarin has been demonstrated; altered coagulation parameters and/or bleeding and death have been reported. Clinically significant increases in PT and INR have been observed within days to months after starting Xeloda, and infrequently within one month of stopping Xeloda. For patients receiving both drugs concomitantly, frequent monitoring of INR or PT is recommended. Age greater than 60 and a diagnosis of cancer independently predispose patients to an increased risk of coagulopathy.

The most common adverse events ( $\geq 20\%$ ) of Xeloda in combination with docetaxel were lymphocytopenia, leukopenia, neutropenia/granulocytopenia, anemia, diarrhea, stomatitis, hand-and-foot syndrome, nausea, alopecia, thrombocytopenia, vomiting, edema, abdominal pain, pyrexia, asthenia, fatigue, constipation, and hyperbilirubinemia. Adverse events were more common in patients  $\geq 60$  years of age. Patients with severe diarrhea should be carefully monitored. Xeloda is contraindicated in patients who have a known hypersensitivity to 5-fluorouracil,

and in patients with severe renal impairment. For patients with moderate renal impairment, dose reduction is required. As with any cancer therapy, there is a risk of side effects, and these are usually manageable and reversible with dose modification or interruption.

**FOR FURTHER**

**INFORMATION**

**VISIT THESE**

**WEBSITES:**

[WWW.XELODA.COM](http://WWW.XELODA.COM)

[WWW.TAXOTERE.COM](http://WWW.TAXOTERE.COM)

[WWW.AVENTISONCOLOGY.COM](http://WWW.AVENTISONCOLOGY.COM)

[WWW.ROCHEUSA.COM](http://WWW.ROCHEUSA.COM)

[WWW.RCMED.COM](http://WWW.RCMED.COM)

To further evaluate the role of Xeloda in breast and colorectal cancer in addition to numerous other solid tumors, there are multiple clinical trials currently on-going and planned. For further information on Xeloda, please visit [www.xeloda.com](http://www.xeloda.com) or call Roche at 800-526-6367 for full prescribing information.

Xeloda is a registered trademark of Hoffmann-La Roche Inc.

**ABOUT TAXOTERE**

Taxotere, a drug in the taxoid class of chemotherapeutic agents, inhibits cancer cell division by essentially "freezing" the cell's internal skeleton, which is comprised of microtubules. Microtubules assemble and disassemble during a cell cycle. Taxotere promotes their assembly and blocks their disassembly, thereby preventing cancer cells from dividing and

resulting in cancer cell death. Taxotere is currently approved in the United States to treat patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy, and patients with locally advanced or metastatic NSCLC after failure of prior platinum-based chemotherapy. According to Aventis, the most common severe side effects associated with Taxotere include low blood cell count, fatigue, fluid retention and mouth sores.

The most common non-severe side effects included hair loss, neurosensory, cutaneous, nail changes, nausea and diarrhea. These side effects are generally reversible and manageable. A premedication regimen with corticosteroids is recommended in order to prevent or reduce hypersensitivity and fluid retention. Taxotere is not appropriate therapy for patients with significant liver impairment or a low white blood cell count.

Visit: [www.taxotere.com](http://www.taxotere.com) or [www.aventisoncology.com](http://www.aventisoncology.com) for complete Taxotere prescribing information, including boxed WARNING.

**ABOUT ROCHE**

Hoffmann-La Roche Inc. (Roche), based in Nutley, N.J., is the U.S. prescription drug unit of the Roche Group, a leading research-based health care enterprise that ranks among the world's leaders in pharmaceuticals, diagnostics and vitamins. Roche discovers, develops, manufactures and markets numerous important prescription drugs that enhance people's health, well-being and quality of life. Among the company's areas of therapeutic interest are: dermatology; genitourinary disease; infectious diseases, including influenza; inflammation, including arthritis and osteoporosis; metabolic diseases, including obesity and diabetes; neurology; oncology; transplantation; vascular diseases; and virology, including HIV/AIDS and hepatitis C.

For more information on the Roche pharmaceuticals business in the United States, visit the company's web site at: [www.rocheusa.com](http://www.rocheusa.com)

Taxotere is manufactured by Aventis.