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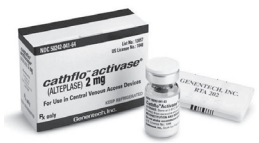
Associate Editor

PHARMACY CORNER

Agent to Restore Central Venous Catheter Function Approved

Genentech (South San Francisco, CA) has received U.S. Food and Drug Administration approval for its thrombolytic agent Cathflo™ Activase® (alteplase) for the restoration of function to central venous access devices.



Each year in the United States, an estimated five million central venous catheters are placed to provide patients with life-saving medications and critical treatment. Up to 25% of these catheters may become occluded or blocked. As many as 60% of occlusions are caused by thrombosis, the formation of a blood clot within or on the tip of the catheter that obstructs the flow of fluids into or out of the body. Current treatments include surgical removal and replacement of the venous access device, which can be uncomfortable, expensive, and potentially risky. The approval of Cathflo Activase addresses the need for a safe and effective method to restore the function of occluded central venous catheters.

Cathflo Activase is a thrombolytic enzyme (serine protease) that promotes fibrin-enhanced conversion of plasminogen to plasmin. The enzyme binds to fibrin in a thrombus and converts the entrapped plasminogen to plasmin, thereby initiating local fibrinolysis. In phase III trials, Cathflo Activase was 88% effective in restoring flow to catheter lines. Nurses should avoid using excessive pressure when instilling Cathflo Activase, as force could rupture the catheter or expel the clot into circulation. Little, if any, Cathflo Activase reaches systemic circulation in normal use. Cathflo Activase is available in a 2 mg single-patient-use vial.

For more information on Cathflo Activase, contact Genentech at 800-821-8590 or visit the Genentech Web site at www.genentech.com.

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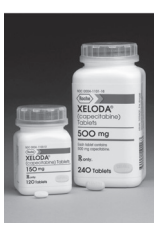
Combination Therapy Approved for Metastatic Breast Cancer

Roche (Nutley, NJ) announced that the U.S. Food and Drug Administration has approved oral Xeloda® (capecitabine) in combination with infusions of Taxotere® (docetaxel, Aventis Pharmaceuticals, Bridgewater, NJ) for patients with metastatic breast cancer refractory to anthracycline therapy. Xeloda belongs to a class of drugs called the fluoropyrimidines. It works through enzymatic activation to the chemotherapeutic agent 5-fluorouracil (5-FU). The human body produces the enzyme thymidine phosphorylase (TP), which converts Xeloda into 5-FU. TP is higher at the tumor site than surrounding normal tissue. Taxotere works independently to interrupt tumor cell mitosis.

In a phase III study of 511 patients, the combination of Xeloda and Taxotere extended survival (14.5 months versus 11.5 months) compared with Taxotere alone. In addition, the combination demonstrated superior tumor response and slowed disease progression (6.1 months versus 4.2 months) when compared to Taxotere monotherapy. The combination of Xeloda and Taxotere caused more adverse events than Taxotere alone, including diarrhea, stomatitis, hand-foot syndrome, nausea, and vomiting. These events were manageable with appropriate medical intervention and dose interruptions. Dose reductions decreased the overall incidence of adverse events in subsequent cycles. Patients with severe diarrhea should be monitored carefully and given fluid and electrolyte replacement if they become dehydrated. The incidence of grade 3 or 4 treatment-related adverse events is greater in patients older than 60 receiving Xeloda in combination with docetaxel. Patients receiving Taxotere alone experienced a higher incidence of neutropenic fever, myalgia, and arthralgia.



Xeloda is contraindicated in patients with severe renal impairment or hypersensitivity to 5-FU. Dose reduction is recommended for patients with moderate renal impairment. Patients receiving concomitant capecitabine and oral coumarin-derivative anticoagulant therapy should have their anticoagulant response (international normalized ratio [INR] or prothrombin time) monitored frequently to adjust the anticoagulant dose accordingly. A clinically important Xeloda-warfarin drug-drug interaction was demonstrated in a clinical pharmacology trial. Altered coagulation parameters or bleeding, some leading to death, have been reported in patients taking Xeloda concomitantly with coumarin-derivative anticoagulants, such as warfarin and phenprocoumon. Patients taking phenytoin concomitantly with Xeloda should be monitored carefully for plasma phenytoin levels and may require phenytoin dose reduction.

The most common severe side effects associated with Taxotere include low blood cell count, fluid retention, hypersensitivity, nausea, and diarrhea. These side effects generally are reversible and manageable. A premedication regimen with corticosteroids is recommended to prevent or reduce hypersensitivity and fluid retention. Taxotere is not appropriate therapy for patients with significant liver impairment.

Xeloda (2,500 mg/m^2) is administered to patients twice daily on days 1–14, and patients receive a Taxotere (75 mg/m^2) infusion on day one of each 21-day treatment cycle.

For more information on Xeloda, contact Roche at 800-526-6367 or visit the Xeloda Web site at www.xeloda.com.

GliaSite Radiation Therapy System Receives Marketing Clearance

GliaSite® (Proxima Therapeutics Inc., Alpharetta, GA) Radiation Therapy System (RTS) for brain tumors has received marketing clearance from the U.S. Food and Drug Administration. GliaSite RTS is an internal radiation system that uses a balloon catheter filled with Iotrex™, a liquid radiation source, that is inserted into the cavity created by surgical removal of a malignant brain tumor. The primary benefit of internal radiation is the delivery of high-dose radiation directly to the tumor bed and its margins (where the tumor is most likely to recur) while minimizing the dose received by healthy, nontargeted brain tissue. The treatment can be used to deliver radiation to recurrent brain tumors or to provide a boost dose following external beam radiation for initial tumor occurrences.

During tumor resection surgery, the neurosurgeon positions the balloon portion of the GliaSite catheter within the cavity created by

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