Important Safety Information
for
Campath® (alemtuzemab)

WARNING: CYTOPENIAS, INFUSION REACTIONS, and INFECTIONS

Cytopenias: Serious, including fatal, pancytopenia/marrow hypoplasia, autoimmune idiopathic thrombocytopenia, and autoimmune hemolytic anemia can occur in patients receiving Campath. Single doses of Campath greater than 30 mg or cumulative doses greater than 90 mg per week increase the incidence of pancytopenia.

Infusion Reactions: Campath administration can result in serious, including fatal, infusion reactions. Carefully monitor patients during infusions and withhold Campath for Grade 3 or 4 infusion reactions. Gradually escalate Campath to the recommended dose at the initiation of therapy and after interruption of therapy for 7 or more days.

Infections: Serious, including fatal, bacterial, viral, fungal, and protozoan infections can occur in patients receiving Campath. Administer prophylaxis against Pneumocystis jiroveci pneumonia (PCP) and herpes virus infections.

In clinical trials, the frequency of infusion reactions was highest in the first week of treatment. The following serious, including fatal, infusion reactions have been identified in post-marketing reports: syncope, pulmonary infiltrates, acute respiratory distress syndrome (ARDS), respiratory arrest, cardiac arrhythmias, myocardial infarction, acute cardiac insufficiency, cardiac arrest, angioedema, and anaphylactoid shock.

Prolonged myelosuppression have been reported in patients receiving Campath. Campath treatment results in severe and prolonged lymphopenia with a concomitant increased incidence of opportunistic infections. Assess CD4+ counts after treatment until recovery to ≥ 200 cells/μL. Obtain complete blood counts (CBC) at weekly intervals during Campath therapy and more frequently if worsening anemia, neutropenia, or thrombocytopenia occurs. Withhold Campath for severe cytopenias (except lymphopenia). Discontinue for autoimmune cytopenias or recurrent/persistent severe cytopenias (except lymphopenia).

Administer only irradiated blood products to avoid transfusion associated Graft versus Host Disease (TAGVHD), unless emergent circumstances dictate immediate transfusion.

Routinely monitor patients for CMV infection during Campath treatment and for at least 2 months following completion of treatment. Withhold Campath for serious infections and during antiviral treatment for CMV infection or confirmed CMV viremia. Initiate therapeutic ganciclovir (or equivalent) for CMV infection or confirmed CMV viremia.

Do not administer live viral vaccines to patients who have recently received Campath.

The most common adverse reactions (≥ 10%) were infusion reactions, cytopenias, cytomegalovirus (CMV) and other infections, nausea, emesis, diarrhea, and insomnia.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For important risk and use information, please see full Prescribing Information.