**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use Campath safely and effectively. See full prescribing information for Campath.

**Clinical Trials**

Campath (identimab)

In ankylosing spondylitis, patients with disease activity during morning stiffness.

Serious, including fatal, cytopenia, infusion reactions and infections

- Limit doses to 30 mg (single) and 90 mg (cumulative weekly) doses.
- Higher doses are associated with higher risk of pancytopenia (5.2).
- Escalate dose gradually and monitor patients during infusion. Without therapy for Grade 4 or 3 infusion reactions (5.2).
- Administer prophylaxis against Pneumocystis jiroveci pneumonia (PCP) and herpes virus infections (5.3).

**Dosage and Administration**

- Administer as an IV infusion over 2 hours (2.1).
- Administer as a cumulative dose of 20 mg/day three times per week for 12 weeks (2.2).
- Premedicate with antihistamines and acetaminophen prior to dosing (2.3).

**Contraindications**

None

**Warnings and Precautions**

- Obtain complete blood counts (CBC) and platelet counts at weekly intervals during Campath therapy and at least monthly during treatment-free intervals.
- Do not administer live viral vaccines to patients who have recently received Campath.

**Adverse Reactions**

Most common adverse reactions: cytopenias, infusion reactions, cytomegalovirus (CMV) and other infections, nausea, diarrhea, and nausea.

**Indications and Usage**

Campath is indicated as a single agent for the treatment of B-lymphocytic leukemia (B-CLL).

**Full prescribing information**

See full prescribing information for Campath.

**References**


Neutropenia: In previously untreated patients, the incidence of Grade 3 or 4 neutropenia was 42% with a median time to onset of 21 days and a median duration of 4 days. In previously treated patients, the incidence of Grade 3 or 4 neutropenia was 64% with a median duration of 28 days. Ten percent of previously untreated patients and 17% of previously treated patients received granulocyte colony stimulating factor.

Anemia: In previously untreated patients, the incidence of Grade 3 or 4 anemia was 42% with a median time to onset of 21 days and a median duration of 4 days. In previously treated patients, the incidence of Grade 3 or 4 anemia was 49% with a median duration of 14 days. In previously treated patients, the incidence of Grade 3 or 4 thrombocytopenia was 52% with a median duration of 28 days. Ten percent of previously untreated patients and 17% of previously treated patients received transfusions or both.

Infections: In the study of previously untreated patients, Campath demonstrated an overall infection rate of 50% (median time to onset 20 days) and a median duration of 40 days. The Campath arm versus control arm, and 149 patients with B-CLL previously treated with alkylating agents, fludarabine, or other chemotherapies. Patients were treated with the recommended dose of Campath 30 mg/m² and the recommended dose of chlorambucil 15 mg/m² every 12 weeks. Partial response rates of 21% to 31% and complete response rates of 0% to 2% were observed. Infections of all grades were reported in 90% of Campath treated patients and 81% of chlorambucil treated patients. Neutropenia or other infections were reported in approximately 85% of patients across all studies. Grade 3-4 infections were reported in 3% to 12% of Campath studies and 0% to 2% in chlorambucil studies.

Partial response rates of 21 to 31% and complete response rates of 0 to 2% were observed. Infections of all grades were reported in 90% of Campath treated patients and 81% of chlorambucil treated patients.

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After the last 30 mg dose, the mean volume of distribution (Vd.) of Campath was 6.3 L/kg. The terminal half life of Campath was 11 days (range 8 to 19 days) after the last 30 mg dose. Neutropenia was a common adverse reaction in patients treated with Campath. The mean time to onset of Grade 3 or 4 neutropenia was 28 days (median 14 days) and a median duration of 28 days. Ten percent of previously untreated patients and 17% of previously treated patients received granulocyte colony stimulating factor.

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