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Its only indication that has received regulatory approval is Chronic lymphocytic leukaemia (CLL). Each single-use vial contains either 100 mg ofatumumab in 5 mL of solution or 1,000 mg ofatumumab in 50 mL of solution. Zerroft® (ofatumumab). Injection, for intravenous infusion.

Zerroft 100 mg/ 5 mL
® 1,000 mg/ 50 mL of solution.
Ofatumumab (Injection)
HUMAX-CD20 IS A FULLY HUMAN MONOCLONAL
ANTIBODY (FOR THE CD20 PROTEIN)



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Zerroft® (Ofatumumab Injection) also known as HuMax-CD20, is a fully human monoclonal antibody (for the CD20 protein) which appears to inhibit early-stage B lymphocyte activation. It is FDA approved for treating chronic lymphocytic leukemia that is refractory to fludarabine and alemtuzumab (Campath) and has also shown potential in treating Follicular non-Hodgkin's lymphoma, Diffuse large B cell lymphoma, rheumatoid arthritis and relapsing remitting multiple sclerosis. Zerroft® (Ofatumumab Injection) has also received conditional approval in Europe for the treatment of refractory chronic lymphocytic leukemia. This makes ofatumumab the first marketing application for an antibody produced by Genmab, as well as the first human monoclonal antibody which targets the CD20 molecule that will be available for patients with refractory CLL.

Zerroft® (Ofatumumab Injection) is a human monoclonal antibody which targets an epitope in the CD20 molecule encompassing parts of the small and large extracellular loops. Zerroft® (Ofatumumab Injection) directs the body's immune system to fight normal and cancerous B-cells. Ofatumumab attaches to the CD20 molecule, which is found on the surface of B-cells, the type of cell which becomes cancerous in chronic lymphocytic leukemia (CLL). The CD20 molecule is also found on over 90% of B-cell lymphomas, as well as other lymphoid tumors of B-cell origin. In types of cancer such as these, B-cells can over-proliferate and treatment is needed to reduce their number. Zerroft® (Ofatumumab Injection) is approved in the United States in combination with chlorambucil to treat previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate. Ofatumumab is also approved to treat CLL in patients who are refractory to fludarabine and alemtuzumab in the US, EU, Japan and other territories.

Zerroft® (ofatumumab) is a CD20-directed cytolytic monoclonal antibody indicated:

- in combination with chlorambucil, for the treatment of previously untreated patients with chronic lymphocytic leukemia (CLL) for whom fludarabine-based therapy is considered inappropriate.
- for the treatment of patients with CLL refractory to fludarabine and alemtuzumab.

Store **Zerroft**® refrigerated between 2° to 8°C (36° to 46°F). Do not freeze. Vials should be protected from light

Food and Drug Administration (FDA) approved .Prescription Only (POM)

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