

RAPTIVA[®]
[efalizumab]

For injection, subcutaneous

WARNING:

RISK OF PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML)

- **RAPTIVA increases the risk for PML, a rapidly progressive viral infection of the central nervous system that has no known treatment and that leads to death or severe disability. The risk of PML may markedly increase with longer duration of RAPTIVA exposure. The time dependent threshold when the risk for PML increases is unknown (see WARNINGS).**
 - **Patients on RAPTIVA should be monitored frequently to ensure they are receiving significant clinical benefit, to ensure they understand the significance of the risk of PML, and for any sign or symptom that may be suggestive of PML (see WARNINGS).**
 - **RAPTIVA dosing should be withheld immediately at the first sign or symptom suggestive of PML. For diagnosis, brain magnetic resonance imaging (MRI) and, when indicated, cerebrospinal fluid analysis for JC viral DNA are recommended (see WARNINGS).**

RISK OF SERIOUS INFECTIONS

- **Infections, including serious infections leading to hospitalizations or death, have been observed in patients treated with RAPTIVA (see WARNINGS and ADVERSE REACTIONS). These infections have included bacterial sepsis, viral meningitis, invasive fungal disease and other opportunistic infections. Patients should be educated about the symptoms of infection and be closely monitored for signs and symptoms of infection during and after treatment with RAPTIVA. If a patient develops a serious infection, RAPTIVA should be discontinued and appropriate therapy instituted.**

DESCRIPTION

RAPTIVA[®] (efalizumab) is an immunosuppressive recombinant humanized IgG1 kappa isotype monoclonal antibody that binds to human CD11a. Efalizumab has a molecular weight of approximately 150 kilodaltons and is produced in a Chinese hamster ovary mammalian cell expression system in a nutrient medium containing the antibiotic gentamicin. Gentamicin is not detectable in the final product.

RAPTIVA is supplied as a sterile, white to off-white, lyophilized powder in single-use glass vials for subcutaneous (SC) injection. Reconstitution of the single-use vial with 1.3 mL of the supplied sterile water for injection (non-USP) yields approximately 1.5 mL of solution to deliver 125 mg per 1.25 mL (100 mg/mL) of RAPTIVA. The sterile water for injection supplied does not comply with USP requirement for pH. After