belatacept (be-lat-a-sept)

Nudix

**Classification**

Therapeutic: immunosuppressants
Pharmacologic: fusion proteins

**Pregnancy Category C**

**Indications**

Prevention of organ rejection following kidney transplant in adult patients; in combination with traditional induction, immunosuppressive and maintenance agents.

**Action**

Binds to CD80 and CD86 sites, thereby blocking T-cell costimulation; results in inhibition of T-lymphocyte proliferation and cytokine production. Therapeutic Effects: Prolonged graft survival with decreased production of anti-donor antibodies following kidney transplantation.

**Pharmacokinetics**

Absorption: IV administration results in complete bioavailability.

Distribution: Unknown.

Metabolism and Excretion: Unknown.

Half-life: 9.8 days.

**Contraindications/Precautions**

Contraindicated in: Ebstein-Barr virus (EBV) seronegativity or unknown EBV serostatus; Liver transplantation; Lactation: Avoid breast feeding. Use Cautiously in: Cytomegalovirus (CMV) infection/T-cell depleting therapy (q risk of post-transplant lymphoproliferative disorder [PTLD]), CMV prophylaxis recommended for 3 mos following transplant; Change in body weight ≥10% (dose adjustment recommended); Unknown tuberculosis status (latent infection should be treated prior to use); Evidence of polyoma virus-associated nephropathy (PVAN) may necessitate immunosuppression; Use only if potential benefit to mother outweighs potential risk to fetus; OB: Use only if potential benefit to mother outweighs potential risk to fetus; Pedi: Safety and effectiveness not established.

**Adverse Reactions/Side Effects**

CNS: PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML), headache.

Resp: cough.

CV: hypertension, peripheral edema.

GI: constipation, diarrhea, nausea, vomiting.

GU: proteinuria.

Endo: new-onset diabetes mellitus.

F and E: hyperkalemia, hypokalemia.

Hemat: anemia, leukopenia.

Misc: POST-TRANSPLANT LYMPHOPROLIFERATIVE DISORDER (PTLD), q RISK OF MALIGNANCY, SERIOUS INFECTIONS, fever, graft dysfunction.

**Interactions**

Drug-Drug: May potentially alter the effects of drugs metabolized by the CYP 450 enzyme system. May decrease antibody response to and q risk of adverse reactions from live virus vaccines; avoid use during treatment. May q blood levels, effects and toxicity of mycophenolic acid.

**Route/Dosage**

Prescribed dose must be evenly divisible by 12.5 to ensure accurate preparation.

IV (Adults): Initial phase—10 mg/kg on day of transplant/prior to implantation, day 5 (96 hr after day 1 dose), end of week 2, 4, 8 and 12 post transplantation; maintenance phase—10 mg/kg end of week 16 and every four weeks (q 3 days) thereafter.

**NURSING IMPLICATIONS**

**Assessment**

- Assess for signs of organ rejection throughout therapy.
- Assess for signs of progressive multifocal leukoencephalopathy (hemiparesis, apathy, confusion, cognitive deficiencies, and ataxia) periodically during therapy.
- Monitor for signs and symptoms of infection (fever, chills) periodically during therapy.
- Assess for signs and symptoms of post-transplant lymphoproliferative disorder (changes in mood or behavior, confusion, problems thinking, loss of memory, changes in walking or talking, decreased strength or weakness on one side of the body, changes in vision) during and for at least 1 year post-transplant.
Monitor for infusion reactions (hypotension, hypertension) during therapy.

**Lab Test Considerations:** May cause hyperkalemia, hypokalemia, hyperphos- phatemia, hyperglycemia, hypercalcemia, hypercholesterolemia, hypomagnesemia, and hyperuricemia.

**Potential Nursing Diagnoses**

- Risk for infection (Adverse Reactions)

**Implementation**

- Pre-medication is not required.
- Cortisone doses should be consistent with clinical trials experience. Cortisone doses were tapered to between 10–20 mg/day by first 6 weeks after transplant, then remained at 10 mg (5–10 mg) per day for first 3 months after transplant.
- Treat patient for latent tuberculosis prior to therapy.
- Prophylaxis for *Pneumocystis jiroveci* is recommended after transplant.

**Intermittent Infusion:** Calculate number of vials required for total infusion dose. Reconstitute contents of each vial with 10.5 mL of 0.9% NaCl or D5W using the silicone-free disposable syringe provided and an 18–21 gauge needle for a concentration of 25 mg/mL. Direct stream of diluent to wall of vial. Remove and invert vial gently, do not shake to avoid foaming. Solution is clear to slightly opalescent and colorless to pale yellow; do not use of opaque particles, discoloration, or other particles are present. Calculate total volume needed for infusion dose. **Different:** Dilute further with 0.9% NaCl if reconstituted with sterile water for injection, 0.9% NaCl if reconstituted with D5W, or with D5W if reconstituted with DPH. **Concentration:** 2 mg/mL. Withdraw amount of diluent from infusion container equal to volume of infusion dose, and reconstitute amount of belatacept solution from vial, inject into infusion container, and rotate gently to mix. Typical infusion volume is 100 mL, but may range from 50–250 mL. Transfer to infusion tubing by infusion container immediately. Infusion must be completed within 24 hr of reconstitution. May be refrigerated and protected from light for 24 hr. Do not administer solution in vials. **Rate:** Infuse over 30 min using a non-pyrogenic, low-protein-binding filter with 0.2–1.2 micron pore size.

**Y-Site Incompatibility:** Do not mix or infuse in same line with other agents.

**Patient/Family Teaching**

- Reinforce the need for lifelong therapy to prevent transplant rejection. Review symptoms of rejection for the transplanted organ, and stress need to notify healthcare professional immediately if signs of rejection or infection occur.
- Advise patient to avoid contact with persons with contagious diseases.
- Informed of the increased risk of skin cancer and other malignancies. Advise patient to use sunscreens with high protection factor and wear protective clothing to decrease risk of skin cancer.
- Advise patient to notify healthcare professional of all Rx or OTC medications, vitamins, herbal products being taken and to consult with healthcare professional before taking other medications.
- Advise patient to notify healthcare professional immediately if signs or symptoms of infection, post-transplant lymphoproliferative disorder or progressive multifocal leukoencephalopathy occur.
- Advise patient to avoid live vaccines during therapy.
- Advise female patients to avoid live vaccines before and after pregnancy.
- Emphasize the importance of routine follow-up laboratory tests.

**Evaluation/Desired Outcomes**

- Prevention of rejection of transplanted kidneys.

**Why was this drug prescribed for your patient?**