



## Prograf® (tacrolimus) – First-time generic

- On August 25, 2017, the [FDA approved](#) an [AP-rated](#) generic version of Astellas' [Prograf \(tacrolimus\)](#) 5 mg/mL injection.
- Prograf is approved for the prophylaxis of organ rejection in patients receiving allogeneic kidney, heart, or liver transplants.
  - It is recommended that Prograf be used concomitantly with [azathioprine](#) or [mycophenolate mofetil](#) and adrenal corticosteroids in kidney and heart transplant patients.
  - It is recommended that Prograf be used concomitantly with adrenal corticosteroids in liver transplant patients.
  - Prograf should not be used simultaneously with [cyclosporine](#).
  - Prograf injection should be reserved for patients unable to take Prograf capsules orally.
  - Use with [sirolimus](#) is not recommended in liver and heart transplant. The safety and efficacy of Prograf with sirolimus has not been established in kidney transplant.
- Prograf is also available generically as an oral capsule in 0.5 mg, 1 mg, and 5 mg strengths.
- Prograf carries a boxed warning for malignancies and serious infections.
- Hospira/Pfizer's launch plans for generic Prograf injection are pending.



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