



## Envarsus XR<sup>®</sup> (tacrolimus) – New indication

- On December 19, 2018, [Veloxis announced](#) the FDA approval of [Envarsus XR \(tacrolimus\)](#) extended-release tablets, for the prophylaxis of organ rejection in *de novo* kidney transplant patients in combination with other immunosuppressants.
  - Envarsus XR is also indicated for the prophylaxis of organ rejection in kidney transplant patients converted from [tacrolimus](#) immediate-release formulations, in combination with other immunosuppressants.
- The new indication for Envarsus XR was based on a 12-month study enrolling 543 patients who received a *de novo* kidney transplant. Patients received once daily Envarsus XR or twice daily immediate release tacrolimus and concomitant immunosuppressives. Efficacy failure rates were defined as biopsy-proven acute rejection, graft failure, death, and/or lost to follow-up at 12 months.
  - The overall treatment difference of efficacy failure of Envarsus XR vs. tacrolimus immediate-release was -1.0% (95% CI: -7.6%, 5.6%)
- The most common adverse reactions ( $\geq 15\%$ ) with Envarsus XR use in *de novo* kidney transplant patients were diarrhea, anemia, urinary tract infection, hypertension, tremor, constipation, diabetes mellitus, peripheral edema, hyperkalemia and headache.
- The recommended starting dose of Envarsus XR in *de novo* kidney transplant is 0.14 mg/kg/day taken orally on an empty stomach consistently at the same time of the day, preferably in the morning to ensure consistent and maximum possible drug exposure, at least 1 hour before a meal or at least 2 hours after a meal. The Envarsus XR dosage should be titrated based on clinical assessments of rejection and tolerability and to achieve whole blood trough concentration ranges of 6 to 11 ng/mL for month one and 4 to 11 ng/mL after month one.
  - Envarsus XR is not interchangeable or substitutable with tacrolimus extended-release capsules, tacrolimus capsules, and tacrolimus for oral suspension. Under or overexposure to tacrolimus may result in graft rejection or other serious adverse reactions.
  - Consult the Envarsus XR drug label for dosing for its other indication and further dosing recommendations.



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