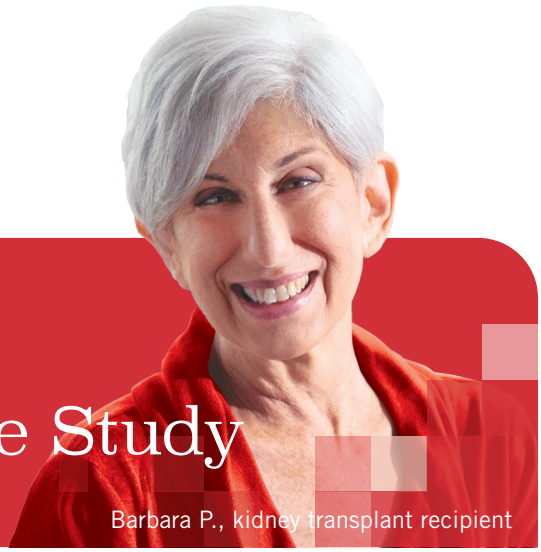
AlloSure® KIDNEY



Introducing **ADMIRAL:** A Landmark Surveillance Study

The largest prospective cohort of kidney transplant recipients followed for three years with over 200 biopsy-paired dd-cfDNA results.[1]

Assessing Dd-cfDNA Monitoring Insights of Renal Allografts with Longitudinal Surveillance

Multi-Center
7 Major Transplant Centers

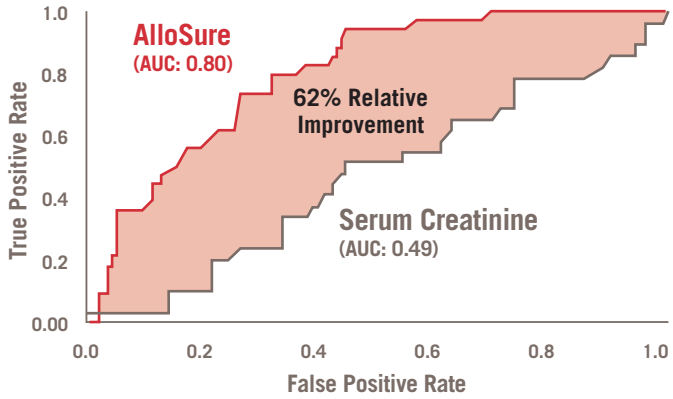
Robust Patient Cohort
1,092 Patients with 3,965 AlloSure Draws

Real-World Evidence
Represents US Transplant Demographics

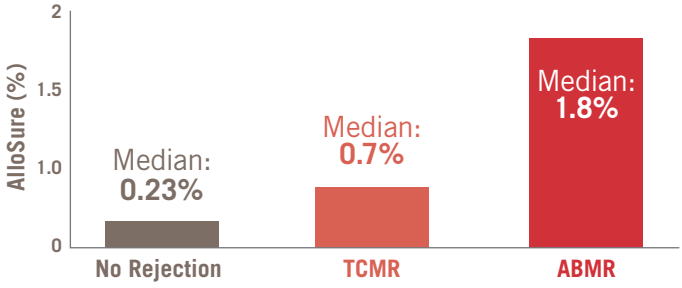
Surveillance Testing
Median of 6 AlloSure Draws Per Patient

Long-Term Outcomes
Patients Monitored Up to 3 Years

62% Improvement Over Serum Creatinine in Identifying Subclinical and Clinical Rejection[1]

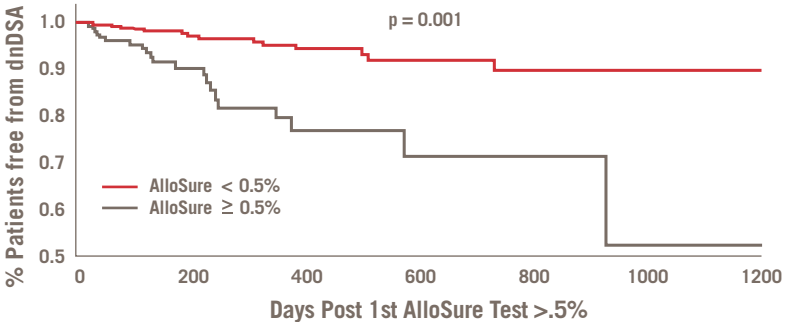


AlloSure Detects Both TCMR and ABMR[1]



AlloSure® KIDNEY

Unleash the Power to Predict Early Graft Injury* and dnDSA Detection

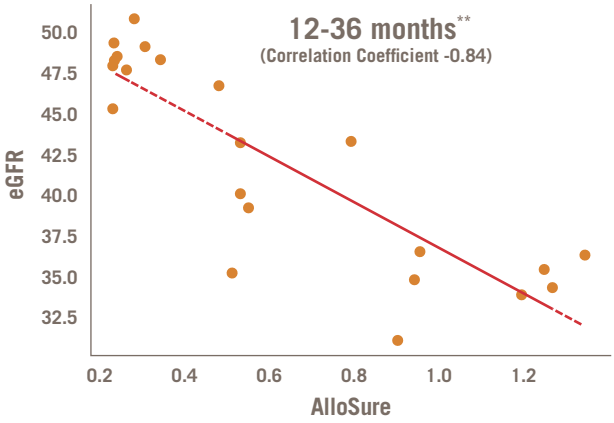


AlloSure scores rose a median of 91 days before detection of dnDSA[1]

AlloSure Elevations (≥0.5%) Were Associated with a Nearly 3-fold Elevation in the Detection of Future dnDSA[1]

Higher AlloSure Scores Correlated with eGFR Decline[1]

Persistently Elevated AlloSure (>1 result, ≥0.5%) Nearly Doubles the Risk of >25% Decline in Patients' eGFR over 3 years[1]



AlloSure is a Broadly-Adopted and Clinically Validated Surveillance Tool

14 Center Prospective Validation Trial

1 in 3 Newly Transplanted Kidney Patients Receives AlloSure

>160 Centers Actively Using AlloSure

40+ Journal Publications

Covered by Medicare When Coverage Criteria is met

For more information visit caredx.com

CareDx® Your Partner in Transplant Care™

*Injury defined in ADMIRAL as: Out of range tacrolimus, BK viremia, dnDSA positive, urinary tract infection, proteinuria, allograft rejection, and recurrent FSGS

**No statistical significance within first year

1. Bu L. et. al. Kidney International 2021.

Partnering Together to Improve the Future of Transplant

Visit **PartnersInTransplant.com** to Learn More

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LIVING DONOR CIRCLE OF EXCELLENCE MEMBER

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Partnering Together to Promote Transplant Success

For more than 20 years, Sanofi has been dedicated to advancing the field of kidney transplantation. This long-standing commitment is expressed in part through a variety of philanthropic and education-driven initiatives to help improve the lives of kidney transplant patients.

Dedication to Education: Kidney Transplant Curriculum

Sanofi has collaborated with experts in the transplant field to create a collective educational curriculum that can be tailored to the needs of your individual transplant center.

Empowering Patients

Sanofi is dedicated to helping patients take a more active role in their treatment journey, empowering self-advocacy, and increasing access to educational resources for those within the kidney transplant community.

Partnering Through Innovation

Sanofi supports patient organizations and professional associations in their efforts to advance care within the kidney transplant community and improve patient outcomes.

Sharing Knowledge

Sanofi is committed to raising awareness of the challenges and opportunities in kidney transplantation by sharing educational resources for patients and providers.

Visit **PartnersInTransplant.com** to Learn More

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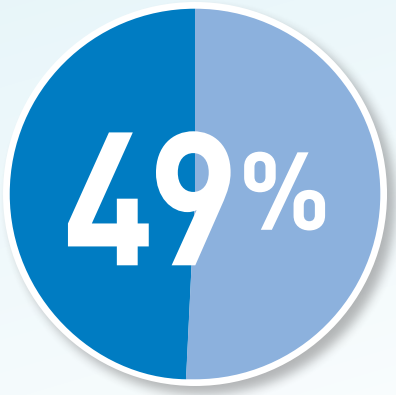
ENVARSUS XR:
Enhance your control

Once-daily
Envarsus XR®
(tacrolimus extended-release tablets)
CONTROL WITH CONFIDENCE

99% of US transplant centers have used ENVARSUS XR for renal transplant immunosuppression[1]



49% of US renal transplant centers have added ENVARSUS XR to protocol[1]

Control, consistency, and convenience for immunosuppressive therapy.[2-7]

Choose ENVARSUS XR.

INDICATIONS AND USAGE

ENVARSUS XR is indicated 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.

IMPORTANT SAFETY INFORMATION

WARNING: MALIGNANCIES AND SERIOUS INFECTIONS
Increased risk for developing serious infections and malignancies with ENVARSUS XR or other immunosuppressants that may lead to hospitalization or death

Please see Important Safety Information continued on reverse side and full Prescribing Information, including Boxed Warning.

CONTRAINDICATIONS

ENVARSUS XR is contraindicated in patients with known hypersensitivity to tacrolimus.

WARNINGS AND PRECAUTIONS

Lymphoma and Other Malignancies: Immunosuppressants, including ENVARSUS XR, increase the risk of developing lymphomas and other malignancies, particularly of the skin. Post-transplant lymphoproliferative disorder (PTLD), associated with Epstein-Barr Virus (EBV), has been reported in immunosuppressed organ transplant patients.

Serious Infections: Immunosuppressants, including ENVARSUS XR, increase the risk of developing bacterial, viral, fungal, and protozoal infections, including opportunistic infections. These infections may lead to serious, including fatal, outcomes.

Not Interchangeable with Other Tacrolimus Products – Medication Errors: Medication errors, including substitution and dispensing errors, between tacrolimus capsules and tacrolimus extended-release capsules were reported outside the U.S. This led to serious adverse reactions, including graft rejection, or other adverse reactions due to under- or over-exposure to tacrolimus. ENVARSUS XR is not interchangeable or substitutable with tacrolimus extended-release capsules, tacrolimus capsules or tacrolimus for oral suspension.

New Onset Diabetes after Transplant: ENVARSUS XR caused new onset diabetes after transplant (NODAT) in kidney transplant patients, which may be reversible in some patients. African-American and Hispanic kidney transplant patients are at an increased risk.

Nephrotoxicity: ENVARSUS XR, like other calcineurin-inhibitors, can cause acute or chronic nephrotoxicity. Consider dosage reduction in patients with elevated serum creatinine and tacrolimus whole blood trough concentrations greater than the recommended range. The risk for nephrotoxicity may increase when ENVARSUS XR is concomitantly administered with CYP3A inhibitors (by increasing tacrolimus whole blood concentrations) or drugs associated with nephrotoxicity.

Neurotoxicity: ENVARSUS XR may cause a spectrum of neurotoxicities. The most severe neurotoxicities include posterior reversible encephalopathy syndrome (PRES), delirium, seizure, and coma; others include tremors, paresthesias, headache, mental status changes, and changes in motor and sensory functions.

Hyperkalemia: Mild to severe hyperkalemia, which may require treatment, has been reported with tacrolimus including ENVARSUS XR. Concomitant use of agents associated with hyperkalemia may increase the risk for hyperkalemia.

Hypertension: Hypertension is a common adverse reaction of ENVARSUS XR therapy and may require antihypertensive therapy.

Risk of Rejection with Strong CYP3A Inducers and Risk of Serious Adverse Reactions with Strong CYP3A Inhibitors: The concomitant use of strong CYP3A inducers may increase the metabolism of tacrolimus, leading to lower whole blood trough concentrations and greater risk of rejection. In contrast, the concomitant use of strong CYP3A inhibitors may decrease the metabolism of tacrolimus, leading to higher whole blood trough concentrations and greater risk of serious adverse reactions. Therefore, adjust ENVARSUS XR dose and monitor tacrolimus whole blood trough concentrations when coadministering ENVARSUS XR with strong CYP3A inhibitors or strong CYP3A inducers.

QT Prolongation: ENVARSUS XR may prolong the QT/QTc interval and cause Torsade de Pointes. Avoid ENVARSUS XR in patients with congenital long QT syndrome. Consider obtaining electrocardiograms and monitoring electrolytes periodically during treatment in patients with congestive heart failure, bradyarrhythmias, those taking certain antiarrhythmic medications or other products that lead to QT prolongation, and those with electrolyte disturbances. When coadministering ENVARSUS XR with other substrates and/or inhibitors of CYP3A, a reduction in ENVARSUS XR dosage, monitoring of tacrolimus whole blood concentrations, and monitoring for QT prolongation is recommended.

Immunizations: Whenever possible, administer the complete complement of vaccines before transplantation and treatment with ENVARSUS XR. Avoid the use of live attenuated vaccines during treatment with ENVARSUS XR. Inactivated vaccines noted to be safe for administration after transplantation may not be sufficiently immunogenic during treatment with ENVARSUS XR.

Pure Red Cell Aplasia: Cases of pure red cell aplasia (PRCA) have been reported in patients treated with tacrolimus. If PRCA is diagnosed, consider discontinuation of ENVARSUS XR.

ADVERSE REACTIONS

De Novo kidney transplant patients: Most common adverse reactions (incidence ≥15%) reported with ENVARSUS XR are diarrhea, anemia, urinary tract infection, hypertension, tremor, constipation, diabetes mellitus, peripheral edema, hyperkalemia and headache.

Conversion of kidney transplant patients from immediate-release tacrolimus: Most common adverse reactions (incidence ≥10%) reported with ENVARSUS XR include: diarrhea and blood creatinine increased.

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on postmarketing surveillance, registry and animal data may cause fetal harm. Advise pregnant women of the potential risk to the fetus.

Nursing Mothers: Tacrolimus is present in human milk. Discontinue drug or nursing, taking into account the importance of drug to the mother.

Females and Males of Reproductive Potential: Advise female and male patients of reproductive potential to speak with their healthcare provider on family planning options including appropriate contraception prior to starting treatment with ENVARSUS XR. Based on animal studies, ENVARSUS XR may affect fertility in males and females.

Pediatric Use: The safety and efficacy of ENVARSUS XR in pediatric patients have not been established.

Geriatric Use: Clinical studies of ENVARSUS XR did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

Renal Impairment: Frequent monitoring of renal function is recommended. Lower doses may be required.

Hepatic Impairment: Frequent monitoring of tacrolimus trough concentrations is recommended. With greater tacrolimus whole blood trough concentrations in patients with severe hepatic impairment, there is a greater risk of adverse reactions and dosage reduction is recommended.

Race: African-American patients may require higher doses to attain comparable trough concentrations compared to Caucasian patients. African-American and Hispanic kidney transplant patients are at an increased risk for new onset diabetes after transplant. Monitor blood glucose concentrations and treat appropriately.

To report SUSPECTED ADVERSE REACTIONS, contact Veloxis Pharmaceuticals, Inc. at 1-844-VELOXIS (835-6947) or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see full Prescribing Information, including Boxed Warning.

References: 1. Data on file. Veloxis Pharmaceuticals, Inc.; 2021. **2.** Data on file. Veloxis Pharmaceuticals, Inc.; 2018. **3.** Budde K, Bunnapradist S, Grinyo JM, et al. Novel once-daily extended-release tacrolimus (LCPT) versus twice-daily tacrolimus in de novo kidney transplants: one-year results of phase III, double-blind, randomized trial. *Am J Transplant*. 2014;14(12):2796-2806. **4.** Rostaing L, Bunnapradist S, Grinyó JM, et al. Novel once-daily extended-release tacrolimus versus twice-daily tacrolimus in de novo kidney transplant recipients: two-year results of phase 3, double-blind, randomized trial. *Am J Kidney Dis*. 2016;67(4):648-659. **5.** Trofe-Clark J, Brennan DC, West-Thielke P, et al. Results of ASERTAA, a randomized prospective crossover pharmacogenetic study of immediate-release versus extended-release tacrolimus in African American kidney transplant recipients. *Am J Kidney Dis*. 2018;71(3):315-326. **6.** Bunnapradist S, Rostaing L, Alloway RR, et al. LCPT once-daily extended-release tacrolimus tablets versus twice-daily capsules: a pooled analysis of two phase 3 trials in important de novo and stable kidney transplant recipient subgroups. *Transpl Int*. 2016;29(5):603-611. **7.** ENVARSUS XR [package insert]. Cary, NC: Veloxis Pharmaceuticals, Inc.; 2020.

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