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

Access Guide

Resources for Transplant Teams to easily access ENVARSUS XR, a unique tacrolimus formulation

- Veloxis Transplant Support provides best-in-class assistance and patient resources

Veloxis | Transplant Support

1-844 VELOXIS (835-6947)
Monday-Friday, 9AM - 7PM ET
VeloxisTransplantSupport.com

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

CONTRAINDICATIONS

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

Please see additional Important Safety Information on pages 6 and 7 and see full Prescribing Information & Medication Guide, including Boxed Warning, in pocket.

It's easy to get access

Patient has been prescribed ENVARSUS XR

Start new patients right now with a 30-day free trial*

30 DAYS FREE Vouchers available from EnvarsusXR.com or local representative

Does the patient have coverage?

- **Not Sure** →

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Download the simple enrollment form from EnvarsusXR.com

Affordable coverage identified?

- **Yes!** → **Is patient commercially insured?**
  - **Yes!** → **$0 Co-pay for Commercially Insured Patients***
    $0 Co-pay $0 Co-pay cards available instantly from EnvarsusXR.com
- **No, the patient needs help affording their medication** → **Enroll in Patient Assistance Program***
  Veloxis Transplant Support sends medication to eligible patients free of charge

Access resources the way you want

- Contact your local Veloxis Sales Representative
- Visit EnvarsusXR.com
- Call Veloxis Transplant Support

*See full terms and conditions at EnvarsusXR.com.

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Discover ongoing support and resources for patients

Benefit investigation
- Verify coverage, identifying possible restrictions, and reporting cost sharing by tier

Prior authorization assistance
- Guides you through every step of a payer's process, identifying requirements, and providing templates for statements of medical necessity

Coordination with specialty pharmacies
- Ensures access to ENVARSUS XR prior to filling prescriptions

Prescription fulfillment navigation
- Identifies the most cost-effective method to fill ENVARSUS XR prescriptions

ENVARSUS XR is on CoverMyMeds®
- Partners with EHRs, payers, pharmacies, and providers
- Automates the PA process making it a faster and easier way to review, complete, and track requests

Visit EnvarsusXR.com to download the Patient Enrollment Form and get started

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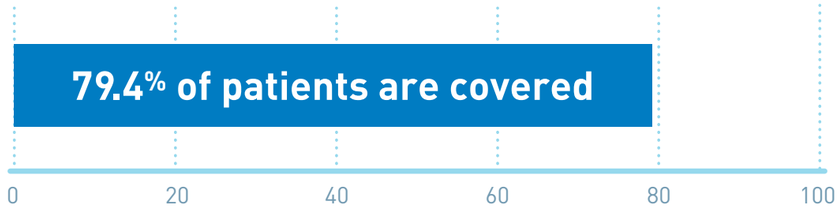
EHRs, electronic health records; PA, prior authorization.

Key access considerations

Most insured patients have access to ENVARSUS XR

- Insurance plans cover ENVARSUS XR better than any other branded tacrolimus formulation



Based on the percent of insured patients in the United States.

Support for Medicare Part B patients

- Centers for Medicare & Medicaid Services (CMS) established a unique J-Code, J7503, to facilitate reimbursement of ENVARSUS XR through Medicare Part B plans

ENVARSUS XR $0 co-pay card overcomes financial barriers

- **Insurance plan structure may be a deterrent**
  - High deductible or lower tier plans may have prohibitive out-of-pocket costs for other drugs, even generics
- **Generics may have a co-pay as high as $35**
  - With the number of medications that a transplant patient needs to stay healthy, even generics may not be affordable

"The limited options to pay for expensive immunosuppressive medications… likely plays a role in medication nonadherence [and] transplant failure."

— American Organ Transplant Association[1]

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Patients benefit from Veloxis Transplant Support

Sarah H, patient

1 Enrolled in Veloxis Transplant Support

2 Benefits investigation was conducted

3 Prior authorization submitted and approved within 24 hours

4 Patient is using $0 co-pay card for ENVARSUS XR prescription

John M, patient

1 Started ENVARSUS XR immediately with the 30-day trial

2 Enrolled in Veloxis Transplant Support

3 Insurance company denied coverage

4 Entered into the Patient Assistance Program and was approved within 24 hours

5 Patient is receiving ENVARSUS XR at no charge

Veloxis is committed to ensuring that all patients have access to ENVARSUS XR

"The average cost of immunosuppressive agents may…. compete with the provision of other basic necessities such as food, clothing and shelter."

— American Organ Transplant Association[1]

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Target Trough. Lower Peak.

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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.

IMPORTANT SAFETY INFORMATION (continued)

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.

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References

1. American Organ Transplant Association. Medication Assistance Program. http://www.aotaonline.org/medication-assistance-program.html. Accessed March 2, 2018.

2. Tremblay S, Nigro V, Weinberg J, Woodle ES, Alloway RR. A steady-state head-to-head pharmacokinetic comparison of all FK-506 (tacrolimus) formulations (ASTCOFF): an open-label, prospective, randomized, two-arm, three-period crossover study. Am J Transplant. 2017;17(2):432-442.

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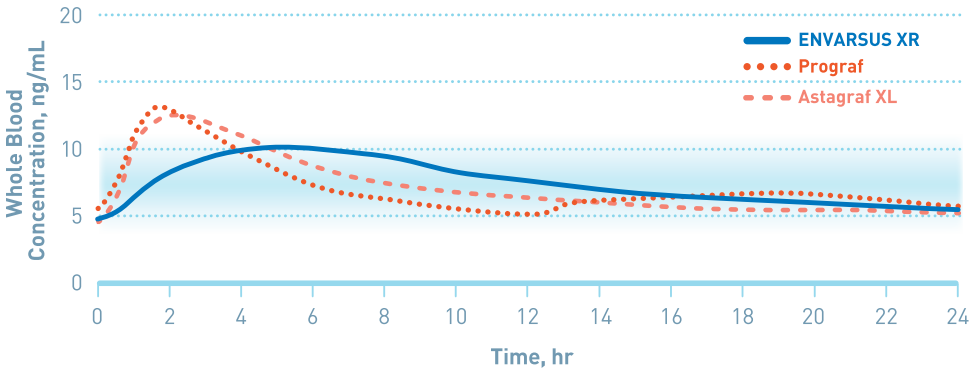
Once-daily ENVARSUS XR—prescribed for specific clinical reasons

ENVARSUS XR versus Prograf® and Astagraf®[2,a]



- Patients on ENVARSUS XR achieved target trough levels with significantly lower peaks than those of Prograf® and Astagraf XL®[2]

[a]Exposure normalized to mean whole blood concentrations of tacrolimus based on conversion factors of 1 (Prograf):1.08 (Astagraf XL):0.7 (ENVARSUS XR).

Study Design: Open-label, randomized, two-sequence, three-period crossover trial of adult stable kidney transplant patients (N=32). After randomization, each patient received Prograf followed by either ENVARSUS XR followed by Astagraf XL or Astagraf XL followed by ENVARSUS XR. Twenty-four-hour PK collections were performed at the end of each 1-week period; a total of 17 or 21 time points were sampled over 24 hours. The primary objective of the study was to evaluate the PK profile of ENVARSUS XR compared with Prograf and Astagraf XL. Clinical benefit of the differences in ENVARSUS XR PK has not been established.[2]

Help patients by making sure they get ENVARSUS XR.
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Veloxis PHARMACEUTICALS

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