Pharmacy Ordering Information

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

Specialty Distributors

Veloxis has worked with the specialty distribution* teams from major wholesalers to ensure availability and ease of ordering ENVARSUS XR.

	Customer Service Number	Customer Service Hours
Bioridge Pharma	1(973) 564-8004	Monday - Friday 8:30am – 5:00pm EST
Cardinal Specialty Pharmaceutical Distribution A division of Cardinal Health	1(866) 476-1340	Monday 9am - 6:00pm EST Tuesday - Friday 9am - 7:00pm EST
Cencora Specialty Healthcare†	1(800) 746-6273	Monday - Thursday 8:00am -7:30pm EST Friday 8:00am - 6:00pm EST
McKesson Plasma and Biologics	1(877) 625-2566	Monday - Friday 9:00am - 7:30pm EST

*List of specialty distributors is limited to top 4 largest by volume; ENVARSUS XR is available at other specialty pharmacies

†You can reach Cencora Specialty Healthcare account set-up at 1 (877) 654-7808, Monday-Thursday 9:30am - 7:30pm EST and Friday 9:30am - 7:00pm EST

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 additional Important Safety Information on pages 3-4 and full Prescribing Information, including Boxed Warning.

Available Strengths, Package Sizes and NDCs

ENVARSUS XR is available in a variety of tablet strengths and package sizes to meet the needs of patients and customers.

Strength	 0.75 mg Tablet		 1 mg Tablet		 4 mg Tablet	
Bottle Size	**30**	**100**	**30**	**100**	**30**	**100**
NDC #	68992-3075-3	68992-3075-1	68992-3010-3	68992-3010-1	68992-3040-3	68992-3040-1
Wholesaler Item #	**Bioridge Pharma**					
	68992-3075-3	68992-3075-1	68992-3010-3	68992-3010-1	68992-3040-3	68992-3040-1
	Cardinal Specialty Pharmaceutical Distribution					
	5151956	5151998	5152020	5152046	5152046	5169974
	Cencora Specialty Healthcare					
	45526	45525	45524	45523	45522	45521
	McKesson Plasma and Biologics					
	3490026	3490018	3489994	3489986	3489978	3489945

Note: Some wholesaler systems may request an 11-digit NDC number. If that is the case, please add a zero "0" just before the last 1 or 3 in the 10-digit NDC number.

Please see additional Important Safety Information on pages 3-4 and full Prescribing Information, including Boxed Warning.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

ENVARSUS XR is contraindicated in patients with known hypersensitivity to tacrolimus or to any of the ingredients in ENVARSUS XR.

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. in some cases leading to adverse reactions. 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 due to ENVARSUS XR and Drug Interactions: ENVARSUS XR, like other calcineurin-inhibitors, can cause acute or chronic nephrotoxicity. In patients with elevated serum creatinine and tacrolimus whole blood trough concentrations greater than the recommended range, consider dosage reduction or temporary interruption of tacrolimus administration. 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. When tacrolimus is used concurrently with CYP3A inhibitors or other known nephrotoxic drugs, monitor renal function and tacrolimus blood concentrations, and adjust dose of both tacrolimus and/or concomitant medications during concurrent use.

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 co-administering ENVARSUS XR with strong CYP3A inhibitors or strong CYP3A inducers. A rapid, sharp rise in tacrolimus levels has been reported after co-administration with strong CYP3A4 inhibitors despite an initial reduction of tacrolimus dose. Early and frequent monitoring of tacrolimus whole blood trough levels is recommended.

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 co-administering ENVARSUS XR with other substrates and/or inhibitors of CYP3A, especially those that also have the potential to prolong the QT interval, 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.

WARNINGS AND PRECAUTIONS (cont'd)

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.

Cannabidiol Drug Interactions: When cannabidiol and ENVARSUS XR are co-administered, closely monitor for an increase in tacrolimus blood levels and for adverse reactions suggestive of tacrolimus toxicity. A dose reduction of ENVARSUS XR should be considered as needed when ENVARSUS XR is co-administered with cannabidiol.

Thrombotic Microangiopathy (TMA) Including Hemolytic Uremic Syndrome and Thrombotic Thrombocytopenic Purpura: Cases of thrombotic microangiopathy (TMA), including hemolytic uremic syndrome (HUS) and thrombotic thrombocytopenic purpura (TTP), have been reported in patients treated with ENVARSUS XR. Transplant patients may have other risk factors which contribute to the risk of TMA. In patients with signs and symptoms of TMA, consider ENVARSUS XR as a risk factor. Concurrent use of ENVARSUS XR and mammalian target of rapamycin (mTOR) inhibitors may contribute to the risk of TMA.

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.

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