

Your guide to a medication designed to help prevent kidney transplant rejection

Direct your future with



Talk to your doctor about ENVARSUS XR as a possible immunosuppression treatment option.



Important Safety Information

What is the most important information I should know about ENVARSUS XR?

ENVARSUS XR can cause serious side effects, including:

Increased risk of cancer. People who take ENVARSUS XR have an increased risk of getting some kinds of cancer, including skin and lymph gland cancer (lymphoma).

Increased risk of infection. ENVARSUS XR is a medicine that affects your immune system. ENVARSUS XR can lower the ability of your immune system to fight infections. Serious infections can happen in people receiving ENVARSUS XR that can cause death.

[Important Safety Information continued on next page.](#)

See the accompanying Medication Guide for more information you should know about ENVARSUS XR.

What is ENVARSUS XR?

ENVARSUS XR is a prescription medicine used with other medicines to help prevent organ rejection in people who have had a kidney transplant. ENVARSUS XR is a form of tacrolimus. Healthcare providers have depended on tacrolimus for over 25 years; it is the most commonly used antirejection medicine in the United States. ENVARSUS XR is an extended-release **tablet** and is not the same as tacrolimus extended-release capsules, tacrolimus immediate-release capsules or tacrolimus for oral suspension. So, even if you know about tacrolimus, it is important to read about and understand ENVARSUS XR and how it is different.

How is ENVARSUS XR different?

Designed using a unique technology, ENVARSUS XR gives your body smooth and stable levels of tacrolimus over 24 hours with once-daily dosing. ENVARSUS XR is also designed to help keep the levels of tacrolimus in the target zone for preventing rejection.

ENVARSUS XR is an extended-release tablet and is not the same as once-daily tacrolimus extended-release capsules (Astagraf XL®) or twice-daily tacrolimus immediate-release capsules (Prograf® or generic tacrolimus).

Other brands of tacrolimus or generic tacrolimus cannot be mixed with ENVARSUS XR. There is no generic substitute for ENVARSUS XR, and the dosing is different from other tacrolimus products. If you are prescribed ENVARSUS XR, be sure it is the only tacrolimus medicine you are taking.

Other tacrolimus products (such as Prograf®) you may be familiar with are taken twice a day. **Do not** take ENVARSUS XR more than once a day. ENVARSUS XR extended-release tablets were designed to work with just one dose all day (24 hours) for kidney transplant patients. **Do not** take any other tacrolimus capsules while you are on ENVARSUS XR. Safely throw away medicine that is out of date or no longer needed.

Your total daily dose of ENVARSUS XR may be lower than the total daily dose you were taking of another tacrolimus product. **Do not** change your dose of ENVARSUS XR unless your healthcare provider tells you to do so.



How many people have tried ENVARSUS XR?

ENVARSUS XR has been studied in more than 1600 participants in clinical trials. Since its approval by the FDA, doctors at kidney transplant centers all over the United States have been prescribing it for their renal transplant patients. In fact, 99% of kidney transplant centers have used ENVARSUS XR.

Important Safety Information (cont)

Call your healthcare provider right away if you have symptoms of an infection such as:

- fever
- cough or flu-like symptoms
- warm, red, or painful areas on your skin
- sweats or chills
- muscle aches

What is ENVARSUS XR?

ENVARSUS XR is a prescription medicine used with other medicines to help prevent organ rejection in people who have had a kidney transplant.

Important Safety Information continued on next page.

Important Safety Information (cont)

ENVARSUS XR is an extended-release tablet and is not the same as tacrolimus extended-release capsules, tacrolimus immediate-release capsules or tacrolimus for oral suspension. Your healthcare provider should decide what medicine is right for you.

Who should not take ENVARSUS XR?

Do not take ENVARSUS XR if you are allergic to tacrolimus or any of the ingredients in ENVARSUS XR.

How do I take ENVARSUS XR?

Take ENVARSUS XR exactly as your healthcare provider tells you to take it. **Do not** stop taking or change your dose of ENVARSUS XR without talking to your healthcare provider.



Take once-daily ENVARSUS XR with fluid (preferably water) on an empty stomach, at least 1 hour before a meal or at least 2 hours after a meal, at the same time every day (preferably in the morning).

Swallow ENVARSUS XR tablets whole.

Do not chew, divide, crush, or dissolve tablets.



Avoid the following while taking ENVARSUS XR:

- Live vaccines such as flu vaccine through your nose, measles, mumps, rubella, polio by mouth, BCG (TB vaccine), yellow fever, chicken pox (varicella), or typhoid
- Exposure to sunlight and UV light such as tanning machines. Wear protective clothing and use a sunscreen
- Eating grapefruit, drinking grapefruit juice, or drinking alcohol

Important Safety Information (cont)

What should I tell my healthcare provider before taking ENVARSUS XR?

Before you take ENVARSUS XR, tell your healthcare provider if you:

- plan to receive any live vaccines. Ask your healthcare provider if you are not sure if your vaccine is a live vaccine.
- have or have had liver, kidney or heart problems.
- have any other medical conditions.
- are pregnant or plan to become pregnant. ENVARSUS XR may harm your unborn baby.

Important Safety Information continued on next page.



What if I miss a dose?

Take a missed dose as soon as possible, but **no longer than 15 hours after missing your scheduled dose**. If the time after you miss your dose is more than 15 hours, skip the missed dose and take the next dose the following morning at your regularly scheduled time. **Do not** take 2 doses at the same time.

If you miss a dose of ENVARSUS XR, call your healthcare provider as soon as possible.

How should I store ENVARSUS XR?

Store ENVARSUS XR at room temperature between 68 °F to 77 °F (20 °C to 25 °C).

Important Safety Information (cont)

- If you are able to become pregnant, you should use effective birth control before and during treatment with ENVARSUS XR. Talk to your healthcare provider about birth control methods that may be right for you.
- Males who have female partners that are able to become pregnant should also use effective birth control before and during treatment with ENVARSUS XR. Talk to your healthcare provider before starting treatment with ENVARSUS XR about birth control methods that may be right for you.

Be sure your tablet is ENVARSUS XR

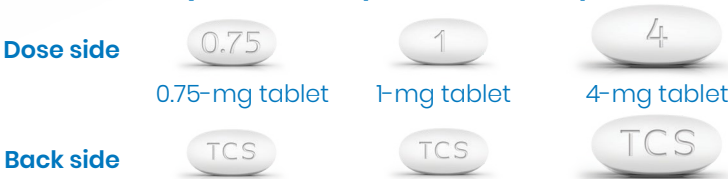
Other brands of tacrolimus or generic tacrolimus **cannot** be used interchangeably with ENVARSUS XR. There is no generic substitute for ENVARSUS XR, and the dosing is different from that of other tacrolimus products.

Be sure your ENVARSUS XR tablet (other tacrolimus products are capsules, not tablets) looks like the one in the picture below and has the correct dosage strength number (to match your prescription) on the dose side of the tablet and the letters "TCS" on the other side.



Tacrolimus capsule;
not ENVARSUS XR

If you are not sure of your tablet, place it on the picture to compare.*



*All ENVARSUS XR tablets are shown actual size.

Your pill bottle from the pharmacy must always say ENVARSUS XR.

If any of these things do not match, call your pharmacist, healthcare provider, and/or transplant coordinator right away.

There are other important directions about taking ENVARSUS XR. Please review the full **Medication Guide**.

Important Safety Information (cont)

- There is a pregnancy registry for females who become pregnant and males who have fathered a pregnancy during treatment with ENVARSUS XR. The purpose of this registry is to collect information about your health and of your baby. To enroll in this voluntary registry, call 1-877-955-6877.
- are breastfeeding or plan to breastfeed. ENVARSUS XR passes into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking ENVARSUS XR.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, natural, herbal or nutritional supplements.

Important Safety Information continued on next page.

Other important directions

Your blood level of ENVARSUS XR will be monitored, and your dose may be adjusted. If your dose is adjusted, be sure to carefully follow your healthcare provider's dosing instructions.

If your pharmacist offers to substitute another brand of tacrolimus or generic tacrolimus, please call your healthcare provider and/or transplant coordinator right away.

If you have an appointment with your family doctor or a healthcare provider outside the transplant center, tell him or her you are taking ENVARSUS XR and that it is not interchangeable with other tacrolimus products.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. The side effects listed in this guide are not all the possible side effects of ENVARSUS XR. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects.

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

Important Safety Information (cont)

ENVARSUS XR may affect the way other medicines work, and other medicines may affect how ENVARSUS XR works.

How should I take ENVARSUS XR?

Take ENVARSUS XR exactly as your healthcare provider tells you to take it. Your healthcare provider may change your dose of ENVARSUS XR if needed. **Do not** stop taking or change your dose of ENVARSUS XR without talking to your healthcare provider.

Take ENVARSUS XR once daily with fluid (preferably water) on an empty stomach, at least 1 hour before or at least 2 hours after a meal, at the same time each day (preferably in the morning).



What are the possible side effects of ENVARSUS XR?

ENVARSUS XR can cause serious side effects, including:

Increased risk of cancer. People who take ENVARSUS XR have an increased risk of getting some kinds of cancer, including skin and lymph gland cancer (lymphoma).

Increased risk of infection. ENVARSUS XR is a medicine that affects your immune system. ENVARSUS XR can lower the ability of your immune system to fight infections. Serious infections can happen in people receiving ENVARSUS XR that can cause death.

Call your healthcare provider right away if you have symptoms of an infection such as:

- fever
- muscle aches
- cough or flu-like symptoms
- sweats or chills
- warm, red, or painful areas on your skin

High blood sugar (diabetes). Your healthcare provider may do certain tests to check for diabetes while you take ENVARSUS XR.

Kidney problems. Kidney problems are serious and common side effects of ENVARSUS XR. Your healthcare provider may do certain tests to check for kidney function while you take ENVARSUS XR.

The most common side effects of ENVARSUS XR include, diarrhea, urinary tract infection, low red blood cell count (anemia), high blood pressure, and constipation.

Important Safety Information (cont)

Take ENVARSUS XR tablets whole. **Do not** chew, divide, crush, or dissolve ENVARSUS XR tablets before swallowing. If you cannot swallow ENVARSUS XR tablets whole, tell your healthcare provider.

If you miss your dose of ENVARSUS XR, it should be taken as soon as possible, but no longer than 15 hours after missing your dose. If the time after you miss your dose is more than 15 hours, the missed dose should be skipped and the next dose should be taken the following morning at your regularly scheduled time. **Do not** take 2 doses at the same time.

If you take too much ENVARSUS XR, call your healthcare provider or go to the nearest hospital emergency room right away.

Important Safety Information continued on next page.

Important Safety Information

What is the most important information I should know about ENVARSUS XR?

ENVARSUS XR can cause serious side effects, including:

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Call your healthcare provider right away if you have symptoms of an infection such as:

- fever
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What is ENVARSUS XR?

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ENVARSUS XR is an extended-release tablet and is not the same as tacrolimus extended-release capsules, tacrolimus immediate-release capsules or tacrolimus for oral suspension. Your healthcare provider should decide what medicine is right for you.

Who should not take ENVARSUS XR?

Do not take ENVARSUS XR if you are allergic to tacrolimus or any of the ingredients in ENVARSUS XR.

What should I tell my healthcare provider before taking ENVARSUS XR?

Before you take ENVARSUS XR, tell your healthcare provider if you:

- plan to receive any live vaccines. Ask your healthcare provider if you are not sure if your vaccine is a live vaccine.
- have or have had liver, kidney or heart problems.
- have any other medical conditions.
- are pregnant or plan to become pregnant. ENVARSUS XR may harm your unborn baby.

Important Safety Information (cont)

- If you are able to become pregnant, you should use effective birth control before and during treatment with ENVARSUS XR. Talk to your healthcare provider about birth control methods that may be right for you.
- Males who have female partners that are able to become pregnant should also use effective birth control before and during treatment with ENVARSUS XR. Talk to your healthcare provider before starting treatment with ENVARSUS XR about birth control methods that may be right for you.
- There is a pregnancy registry for females who become pregnant and males who have fathered a pregnancy during treatment with ENVARSUS XR. The purpose of this registry is to collect information about your health and of your baby. To enroll in this voluntary registry, call 1-877-955-6877.
- are breastfeeding or plan to breastfeed. ENVARSUS XR passes into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking ENVARSUS XR.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, natural, herbal or nutritional supplements.

ENVARSUS XR may affect the way other medicines work, and other medicines may affect how ENVARSUS XR works.

How should I take ENVARSUS XR?

Take ENVARSUS XR exactly as your healthcare provider tells you to take it.

Your healthcare provider may change your dose of ENVARSUS XR if needed. **Do not** stop taking or change your dose of ENVARSUS XR without talking to your healthcare provider.

Take ENVARSUS XR once daily with fluid (preferably water) on an empty stomach, at least 1 hour before or at least 2 hours after a meal, at the same time each day (preferably in the morning).

Take ENVARSUS XR tablets whole. **Do not** chew, divide, crush, or dissolve ENVARSUS XR tablets before swallowing. If you cannot swallow ENVARSUS XR tablets whole, tell your healthcare provider.

If you miss your dose of ENVARSUS XR, it should be taken as soon as possible, but no longer than 15 hours after missing your dose. If the time after you miss your dose is more than 15 hours, the missed dose should be skipped and the next dose should be taken the following morning at your regularly scheduled time. **Do not** take 2 doses at the same time.

If you take too much ENVARSUS XR, call your healthcare provider or go to the nearest hospital emergency room right away.

Important Safety Information continued on next page.

Important Safety Information (cont)

What should I avoid while taking ENVARSUS XR?

Live vaccines such as flu vaccine through your nose, measles, mumps, rubella, polio by mouth, BCG (TB vaccine), yellow fever, chicken pox (varicella), or typhoid.

Exposure to sunlight and UV light such as tanning machines. Wear protective clothing and use a sunscreen.

You should not eat grapefruit or drink grapefruit juice while taking ENVARSUS XR.

You should not drink alcohol while taking ENVARSUS XR.

What are the possible side effects of ENVARSUS XR?

ENVARSUS XR may cause serious side effects, including:

See “What is the most important information I should know about ENVARSUS XR?”

Problems from medication errors such as graft rejection and other serious reactions. People who take ENVARSUS XR have sometimes been given the wrong medicine because some medicines have the same ingredient (tacrolimus) as ENVARSUS XR. **Check your ENVARSUS XR when you get a new prescription to make sure you have received the right medicine.**

- Call your healthcare provider right away if you think you were given the wrong medicine.
- Ask your healthcare provider or pharmacist if you are not sure what ENVARSUS XR should look like.

High blood sugar (diabetes). Your healthcare provider may do certain tests to check for diabetes while you take ENVARSUS XR. Call your healthcare provider right away if you have:

- frequent urination
- drowsiness
- confusion
- nausea, vomiting, or stomach pain
- fruity smell on your breath
- blurred vision
- increased thirst or hunger
- loss of appetite

Kidney problems. Kidney problems are serious and common side effects of ENVARSUS XR. Your healthcare provider may do certain tests to check for kidney function while you take ENVARSUS XR.

Nervous system problems. Nervous system problems are a serious and common side effect of ENVARSUS XR. Call your healthcare provider right

Important Safety Information (cont)

away if you get any of these symptoms while taking ENVARSUS XR. These could be signs of serious nervous system problems:

- confusion
- numbness and tingling
- vision changes
- coma
- headache
- muscle tremors
- seizures

High levels of potassium in your blood. Your healthcare provider may do certain tests to check your potassium level while you take ENVARSUS XR.

High blood pressure. Your healthcare provider will monitor your blood pressure while you take ENVARSUS XR.

Changes in the electrical activity of your heart (QT prolongation).

Severe low blood cell count (anemia)

The most common side effects of ENVARSUS XR are, diarrhea, urinary tract infection, low red blood cell count (anemia), high blood pressure, and constipation.

These are not all the possible side effects of ENVARSUS XR. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ENVARSUS XR?

Store ENVARSUS XR at room temperature between 68° F to 77° F (20° C to 25° C).

Safely throw away medicine that is out of date or no longer needed.

Keep ENVARSUS XR and all medicines out of reach of children.

General information about the safe and effective use of ENVARSUS XR.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ENVARSUS XR for a condition for which it was not prescribed. Do not give ENVARSUS XR to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about ENVARSUS XR. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ENVARSUS XR that is written for health professionals. For more information, go to www.ENVARSUSXR.com or call 1-844-Veloxis (1-844-835-6947).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Our commitment to helping kidney transplant patients

Veloxis is dedicated to ensuring that patients, regardless of their situation, receive their medication. Whether you have commercial or government insurance, or are uninsured/underinsured, we have dedicated financial support for patients taking ENVARSUS XR.*

Pay as little as \$0*.[†]

Out-of-pocket savings for eligible commercially insured patients

Patient Assistance Program*

Provides free medication for eligible patients

For more information on savings and support, please visit www.ENVARSUSXR.com

*Subject to terms, conditions, and eligibility requirements.

[†]Eligible insured patients can save up to a maximum benefit of \$8,550 annually off the patient's co-pay or out-of-pocket expenses of ENVARSUS XR. Patient is responsible for any differential over \$8,550. Offer not valid for cash-paying patients or where drug is not covered by the primary insurance. This offer is valid in the United States. No substitutions permitted. Patients with government insurance are not eligible for assistance provided under the Co-pay Program, including, but not limited to, patients with Medicare, Medicaid, Medigap, TriCare, VA, DoD, or any other federal-, state-, or government-funded government healthcare program. Uninsured and cash-paying patients are not eligible for the Co-pay Program, nor are individuals with commercial insurance who do not have coverage for ENVARSUS XR.

Financial assistance from the Co-pay Program is only available to patients who have been prescribed ENVARSUS XR for an FDA-approved indication.

Personalized post-transplant support

Veloxis Transplant Support offers dedicated support from Specialists who can potentially confirm coverage and identify options for financial assistance. The Specialist is your single point of contact, who may be able to assist with:

Benefit investigation

Verifying coverage, identifying possible restrictions, and clarifying out-of-pocket costs and insurance coverage

Prior authorization assistance

Guides you through every step of your insurer's process, including identifying prior authorization requirements

Alternative funding research

Identifying independent foundations that can assist patients who are underinsured or uninsured

Coordination with specialty pharmacies

Ensuring access to ENVARSUS XR® (tacrolimus extended-release tablets) prior to filling prescription

Veloxis | Transplant Support

1-844-VELOXIS (835-6947)

Monday–Friday, 9 AM–7 PM ET

VeloxisTransplantSupport.com

Veloxis is dedicated to ensuring that all patients, regardless of their situation, receive their medication.

www.ENVARSUSXR.com

See the accompanying Medication Guide for more information you should know about ENVARSUS XR.



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