

ENVARSUS XR[®] Co-pay Program Reimbursement Form

For qualified patients only. Restrictions apply. Patients insured through federal, state, or other government programs, including Medicare and Medicaid, are not eligible for this program. See program rules and eligibility requirements at <https://www.envarsusxr.com/savings-support/>.

If you purchased your medication at the pharmacy and the pharmacist was unable to process your ENVARSUS XR Co-pay Card, you may still utilize the ENVARSUS XR Co-pay Program. Please follow the steps below to obtain your ENVARSUS XR Co-pay Program Benefits.

1. Please print and fill out this form completely.
2. Mail the completed form, copy of your Co-pay Card and original pharmacy receipt to:
ENVARSUS XR Co-pay Program
2250 Perimeter Park Drive, Suite 300
Morrisville, NC 27650

You may also submit your mail-in rebate via fax to 833-871-5347/919-237-7104.

The original pharmacy receipt should include:

1. Patient Name and Address
2. Pharmacy Name, Address, and Phone Number
3. Prescription #, Fill Date, Drug Name, Strength, NDC #, and Quantity
4. Amount of your out-of-pocket payment

First Name

Last Name

Date of Birth (MM/DD/YYYY)

Street Address

City

State

Zip

Phone #

Group # (on your Envarsus XR card)

ID # (on your Envarsus XR card)

Do you have commercial insurance?

 Yes No

Name of the insurer

BIN #

PCN #

Drug Name

Drug Strength

Signature

Do not submit for any claim that was paid for by Medicare, Medicaid, Champus, TriCare, VA or any other government (state or governmentally funded) program, Flexible Spending Account (FSA), Health Savings Account (HSA), Health Reimbursement Account (HRA), or any other pay or discount/co-pay program. Unapproved claims will not be paid.

Please see Important Safety Information on pages 2-3 and full Prescribing Information, including Boxed Warning.

IMPORTANT SAFETY INFORMATION

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

ENVARUSUS XR can cause serious side effects, including:

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

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

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 ENVARUSUS XR?

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

ENVARUSUS 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 ENVARUSUS XR?

Do not take ENVARUSUS XR if you are allergic to tacrolimus or any of the ingredients in ENVARUSUS XR. See the end of this leaflet for a complete list of ingredients in ENVARUSUS XR.

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

Before you take ENVARUSUS 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. ENVARUSUS XR may harm your unborn baby.
 - o If you are able to become pregnant, you should use effective birth control before and during treatment with ENVARUSUS XR. Talk to your healthcare provider about birth control methods that may be right for you.

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

- are breastfeeding or plan to breastfeed. ENVARUSUS XR passes into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking ENVARUSUS XR.

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

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

How should I take ENVARUSUS XR?

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

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

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

If you miss your dose of ENVARUSUS 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 ENVARUSUS XR, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking ENVARUSUS 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 ENVARUSUS XR.

You should not drink alcohol while taking ENVARUSUS XR.

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

IMPORTANT SAFETY INFORMATION *(cont'd)*

What are the possible side effects of ENVARUSUS XR?

ENVARUSUS XR may cause serious side effects, including:

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

Problems from medication errors such as graft rejection and other serious reactions. People who take ENVARUSUS XR have sometimes been given the wrong medicine because some medicines have the same ingredient (tacrolimus) as ENVARUSUS XR. Check your ENVARUSUS 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 ENVARUSUS XR should look like.

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

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

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

Nervous system problems. Nervous system problems are a serious and common side effect of ENVARUSUS XR. Call your healthcare provider right away if you get any of these symptoms while taking ENVARUSUS XR. These could be signs of a serious nervous system problem:

- 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 ENVARUSUS XR.

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

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

Severe low blood cell count (anemia)

The most common side effects of ENVARUSUS 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 ENVARUSUS 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 ENVARUSUS XR?

Store ENVARUSUS 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 ENVARUSUS XR and all medicines out of reach of children.

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

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ENVARUSUS XR for a condition for which it was not prescribed. Do not give ENVARUSUS 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 ENVARUSUS XR. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ENVARUSUS XR that is written for health professionals. For more information, go to www.ENVARUSUSXR.com or call 1-844-Veloxis (1-844-835-6947).

What are the ingredients in ENVARUSUS XR?

Active ingredient: tacrolimus USP

Inactive ingredients: hypromellose USP, lactose monohydrate NF, polyethylene glycol NF, poloxamer NF, magnesium stearate NF, tartaric acid NF, butylated hydroxytoluene NF, and dimethicone NF

Manufactured by: **Rottendorf Pharma GmbH**, 59320 Ennigerloh, North Rhine-Westphalia, Germany

Marketed by: **Veloxis Pharmaceuticals, Inc.** 1001 Winstead Dr, Suite 310, Cary, NC 27513, United States

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.

