

Patient's guide for taking



ENVARSUS XR is taken just **once a day**.

ENVARSUS XR is a tablet; it is the only tacrolimus product available in tablet form.

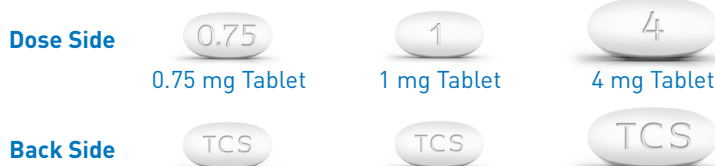


ENVARSUS XR is not substitutable with other tacrolimus products.

Inspect your ENVARSUS XR medicine when you receive a new prescription and before taking it. Other brands of tacrolimus or generic tacrolimus **cannot** be mixed or interchanged with ENVARSUS XR. If the tablet looks different than the picture, contact your Transplant Coordinator as soon as possible to make sure you have the right medicine.



If you are not sure of your tablet, place it on the photo to compare



All ENVARSUS XR tablets are shown actual size.

How to take ENVARSUS XR:

Take your **first dose** of ENVARSUS XR the morning after you take your last evening dose of your current tacrolimus product.

Take once-daily ENVARSUS XR 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 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 sunscreen.
- Eating grapefruit, drinking grapefruit juice, or drinking alcohol.

If you miss a dose:

Take a missed dose as soon as possible but **no longer than 15 hours after missing your scheduled time**. 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 miss a dose of ENVARSUS XR, call your Transplant Coordinator as soon as possible.

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

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.

Please see additional Important Safety Information and accompanying Medication Guide for complete information.

MEDICATION GUIDE
ENVARUSUS XR® (En var' sus XR)
(tacrolimus extended-release tablets)

Read this Medication Guide before you start taking ENVARUSUS XR and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. If you have any questions about ENVARUSUS XR, ask your healthcare provider or pharmacist.

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

ENVARUSUS XR can cause serious side effects, including:

1. **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).
2. **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 doctor 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
- muscle aches
- sweats or chills

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 doctor 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.
 - 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.
 - 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.
 - There is a pregnancy registry for females who become pregnant and males who have fathered a pregnancy during treatment with ENVARUSUS XR. The purpose of this registry is to collect information about your health and of your baby. To enrol in this voluntary registry, call 1-877-955-6877.
- 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 missing 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.

What are the possible side effects of ENVARUSUS XR?

ENVARUSUS XR may cause serious side effects, including:

- See “What 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
 - increased thirst or hunger
 - blurred vision
 - confusion
 - drowsiness
 - loss of appetite
 - fruity smell on your breath
 - nausea, vomiting, or stomach pain
- **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 serious nervous system problems:
 - confusion
 - coma
 - seizures
 - numbness and tingling
 - headache
 - vision changes
 - muscle tremors
- **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

Manufactured for: **Veloxis Pharmaceuticals, Inc.**, Cary, North Carolina 27513, United States

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: December 2018