

Patient's guide for switching to

Once-daily
Envarsus XR[™]
(tacrolimus extended-release tablets)

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

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

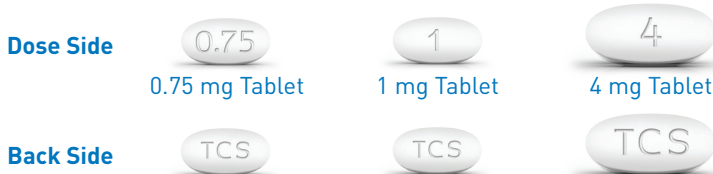


ENVARSUS XR is not substitutable with other tacrolimus products.

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 the same time every day (preferably in the morning).

Swallow ENVARSUS XR tablets whole. Do not chew, divide, or crush 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 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 an extended-release tablet and is not the same as tacrolimus extended-release capsules or tacrolimus immediate-release capsules. Your doctor should decide what medicine is right for you.

Please see additional Important Safety Information, continued on reverse side, and see accompanying Medication Guide for complete information.

Important Safety Information (continued)

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.

Call your doctor 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

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.

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

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?”

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

High blood sugar (diabetes). Your doctor may do certain tests to check for diabetes while you take ENVARSUS XR. Call your doctor 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. Your doctor may do certain tests to check for kidney function while you take ENVARSUS XR.

Nervous system problems. Call your doctor right away if you get any of these symptoms while taking ENVARSUS XR. These could be signs of a serious nervous system problem:

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

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

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

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

The most common side effects of ENVARSUS XR include, 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 doctor or pharmacist.

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

Please see accompanying Medication Guide for complete information.



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

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

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

ENVARSUS XR can cause serious side effects, including:

1. **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).
2. **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 doctor right away if you have symptoms of an infection such as:

- | | | |
|---------------------------------------|---|---|
| <input type="checkbox"/> fever | <input type="checkbox"/> cough or flu-like symptoms | <input type="checkbox"/> warm, red, or painful areas on your skin |
| <input type="checkbox"/> muscle aches | <input type="checkbox"/> sweats or chills | |

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 an extended-release tablet and is not the same as tacrolimus extended-release capsules or tacrolimus immediate-release capsules. Your doctor 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. See the end of this leaflet for a complete list of ingredients in ENVARSUS XR.

What should I tell my doctor before taking ENVARSUS XR?

Before you take ENVARSUS XR, tell your doctor if you:

- plan to receive any live vaccines. Ask your doctor 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. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. ENVARSUS XR can pass into your breast milk. You and your doctor should decide if you will take ENVARSUS XR or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal 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 doctor tells you to take it.
- Your doctor may change your dose of ENVARSUS XR if needed. **Do not** stop taking or change your dose of ENVARSUS XR without talking to your doctor.
- Take ENVARSUS XR once daily with fluid (preferably water) on an empty stomach at the same time each day (preferably in the morning).
- Take ENVARSUS XR tablets whole. **Do not** chew, divide or crush ENVARSUS XR tablets before swallowing. If you cannot swallow ENVARSUS XR tablets whole, tell your doctor.
- 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 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 ENVARSUS XR, call your doctor or go to the nearest hospital emergency room right away.

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 the most important information I should know about ENVARSUS XR?**”
- **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 doctor right away if you think you were given the wrong medicine.
 - Ask your doctor or pharmacist if you are not sure what ENVARSUS XR should look like.
- **high blood sugar (diabetes).** Your doctor may do certain tests to check for diabetes while you take ENVARSUS XR. Call your doctor 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.** Your doctor may do certain tests to check for kidney function while you take ENVARSUS XR.
- **nervous system problems.** Call your doctor right away if you get any of these symptoms while taking ENVARSUS XR. These could be signs of a serious nervous system problem:
 - confusion
 - coma
 - seizures
 - numbness and tingling
 - headache
 - vision changes
 - muscle tremors
- **high levels of potassium in your blood.** Your doctor may do certain tests to check your potassium level while you take ENVARSUS XR.
- **high blood pressure.** Your doctor will monitor your blood pressure while you take ENVARSUS XR.
- **changes in the electrical activity of your heart (QT prolongation).**

The most common side effects of ENVARSUS XR include, 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 doctor or pharmacist.

Call your doctor 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 doctor. You can ask your pharmacist or doctor 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).

What are the ingredients in ENVARSUS 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: April 2017