

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 doctor about your medical condition or your treatment. If you have any questions about ENVARUSUS XR, ask your doctor 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 | ○ warm, red, or painful |
| ○ muscle aches | ○ symptoms | ○ areas on your skin |
| | ○ 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 or tacrolimus immediate-release capsules. Your doctor 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 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. ENVARUSUS 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. ENVARUSUS XR can pass into your breast milk. You and your doctor should decide if you will take ENVARUSUS 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.

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 doctor tells you to take it.
- Your doctor may change your dose of ENVARUSUS XR if needed. **Do not** stop taking or change your dose of ENVARUSUS XR without talking to your doctor.
- Take ENVARUSUS XR once daily with fluid (preferably water) on an empty stomach at the same time each day (preferably in the morning).
- Take ENVARUSUS XR tablets whole. **Do not** chew, divide or crush ENVARUSUS XR tablets before swallowing. If you cannot swallow ENVARUSUS XR tablets whole, tell your doctor.
- 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 doctor 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?**”
- **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 doctor right away if you think you were given the wrong medicine.
 - Ask your doctor or pharmacist if you are not sure what ENVARUSUS XR should look like.
- **high blood sugar (diabetes).** Your doctor may do certain tests to check for diabetes while you take ENVARUSUS 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 ENVARUSUS XR.
- **nervous system problems.** Call your doctor right away if you get any of these symptoms while taking ENVARUSUS 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 ENVARUSUS XR.
- **high blood pressure.** Your doctor will monitor your blood pressure while you take ENVARUSUS XR.
- **changes in the electrical activity of your heart (QT prolongation).**

The most common side effects of ENVARUSUS 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.

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