

Patient's guide for taking

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

CONTROL WITH CONFIDENCE

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

ENVARSUS XR is a tablet not a capsule or oral suspension.



ENVARSUS XR is not substitutable with other tacrolimus products

Check 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 from the picture below, 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 picture to compare*

Dose side



0.75-mg tablet



1-mg tablet



4-mg tablet

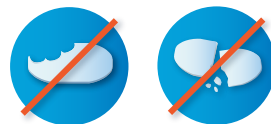
Back side



*All ENVARSUS XR tablets are shown actual size.

How to take ENVARSUS XR:

Take ENVARSUS XR 1-time daily with fluid (preferably with water) on an empty stomach, at least 1 hour before a meal or at least 2 hours after a meal, at the same time each day (preferably in the morning). Decide on a time with your healthcare provider so they will know what time of day to schedule your blood tests.



Swallow ENVARSUS XR tablets whole. **Do not** chew, divide, crush, or dissolve tablets.

Do not stop taking or change your dose of ENVARSUS XR without talking to your healthcare provider.

Avoid the following while taking ENVARSUS XR:

- Live vaccines such as the 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 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 take too much ENVARSUS XR, call your healthcare provider or go to the nearest hospital emergency room right away.

If you have any questions about ENVARSUS XR, call your healthcare provider or pharmacist.

Important Safety Information

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

Please see Important Safety Information and accompanying [Medication Guide and full Prescribing Information, including Boxed Warning](#), in pocket.

Important Safety Information

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

Before you take ENVARSUS XR, tell your healthcare provider about all your medical conditions, including if you: plan to receive any live vaccines, have or have had liver, kidney or heart problems, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

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.

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 and cause serious side effects.

Especially tell your healthcare provider if you take a seizure (anticonvulsant) medicine, medicines to treat infections (antibacterials, antivirals, or antifungals), or other medicines that prevent rejection of a transplanted organ. Do not start or stop a medicine without telling your healthcare provider first.

While taking ENVARSUS XR, avoid live vaccines, exposure to sunlight and UV light such as tanning machines, eating grapefruit or drinking grapefruit juice, and alcohol.

ENVARSUS XR may cause serious side effects, including:

- **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.**
- **High blood sugar (diabetes).** 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, or loss of appetite.

- **Kidney problems.**
- **Nervous system problems.** Call your healthcare provider right away if you get any of these symptoms while taking ENVARSUS XR: confusion, numbness and tingling, vision changes, coma, headache, muscle tremors, or seizures.
- **High levels of potassium in your blood.**
- **High blood pressure.**
- **Changes in the electrical activity of your heart (QT prolongation).**
- **Severe low blood cell count (anemia).**
- **Blood clotting problems.** Tell your healthcare provider right away if you have fever and bruising under the skin that may appear as red dots, with or without unexplained tiredness, confusion, yellowing of the skin or eyes, decreased urination. When taken with sirolimus or everolimus, or when you develop certain infections, the risk of developing these symptoms may increase.

The most common side effects of ENVARSUS XR in people who received a kidney transplant are diarrhea, low red blood cell count (anemia), urinary tract infection, constipation, and swelling in the arms, hands, or legs (peripheral edema).

The most common side effects of ENVARSUS XR in people who are switching from immediate-release tacrolimus to ENVARSUS XR are diarrhea and high blood creatinine.

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

Approved Uses:

- 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, tacrolimus immediate-release capsules or tacrolimus for oral suspension. Your healthcare provider should decide what medicine is right for you.

It is not known if ENVARSUS XR is safe and effective in children.

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.

Please see accompanying [Medication Guide and full Prescribing Information, including Boxed Warning](#), in pocket.



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