Your guide to a medication designed to help prevent rejection





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

Please see full Important Safety Information on pages 10-13.
Please see accompanying Prescribing Information & Medication Guide in pocket.

# What is ENVARSUS XR?

It may seem similar to other medications, but ENVARSUS XR has key differences that may have been a factor in your healthcare provider's prescribing decision.

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 a form of tacrolimus (or TAC). Healthcare providers have depended on TAC for some 20 years; it is the most commonly used anti-rejection medicine in the US. ENVARSUS XR is an extended-release tablet and is not the same as TAC extended-release capsules or TAC immediate-release capsules. So, even if you know about TAC, it is important to read about and understand ENVARSUS XR and how it is different.

# 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.

Call your healthcare provider right away if you have symptoms of an infection such as:

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

# How is ENVARSUS XR different?

Other brands of tacrolimus or generic tacrolimus **cannot** be mixed with ENVARSUS XR. There is no generic substitute for ENVARSUS XR, and the dosing is different from other tacrolimus products. If you are prescribed ENVARSUS XR, be sure it is the only tacrolimus medicine you are taking.

Other tacrolimus products (such as Prograf®) you may be familiar with are taken twice a day. **Do not take ENVARSUS XR more than once a day.** ENVARSUS XR extended-release tablets were designed to work with just one dose all day (24 hours) for kidney transplant patients. **DO NOT** take any other tacrolimus capsules while you are on ENVARSUS XR. If you have been switched

you are on ENVARSUS XR. If you have been switched from another tacrolimus product and you have capsules remaining, dispose of them.

Your total daily dose of ENVARSUS XR may be lower than the total daily dose you were taking of another tacrolimus product. **DO NOT** change your dose of ENVARSUS XR unless your healthcare provider tells you to do so.

# Important Safety Information

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.



Once a

Day Protection

### How do I 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 a meal 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.

# Important Safety Information

What should I tell my healthcare provider before taking ENVARSUS XR? Before you take ENVARSUS 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. ENVARSUS XR may harm your unborn baby.
  - 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.
- are breastfeeding or plan to breastfeed. ENVARSUS XR passes into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking ENVARSUS XR.

# What if I 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.

# How should I store ENVARSUS XR?

Store ENVARSUS XR at room temperature between 68 °F to 77 °F (20 °C to 25 °C).





# Be sure your tablet is ENVARSUS XR

Other brands of TAC or generic TAC **cannot** be used interchangeably with ENVARSUS XR. There is no generic substitute for ENVARSUS XR, and the dosing is different from other TAC products.

Be sure your ENVARSUS XR tablet (other TAC products are capsules, not tablets) looks like the one in the picture below and has the correct dosage strength number (to match your prescription) on one side of the tablet, and TCS on the other side.



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

Dose Side 0.75 1 4 4 mg Tablet 0.75 mg Tablet 1 mg Tablet 4 mg Table

Back Side TCS TCS TCS

All ENVARSUS XR tablets are shown actual size.

Your pill bottle from the pharmacy must always say ENVARSUS XR.

If any of these things do not match, call your pharmacist, healthcare provider, and/or Transplant Coordinator right away.

There are other important directions about taking ENVARSUS XR. Please read the full Prescribing Information & Medication Guide included in the pocket.

# Important Safety Information

#### 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.

# Important Safety Information

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.

#### How should I take ENVARSUS XR?

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

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

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

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 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 ENVARSUS XR, call your healthcare provider or go to the nearest hospital emergency room right away.



# Other important directions

Your blood level of ENVARSUS XR will be monitored and the dose may be adjusted. If adjusted, be sure to carefully follow your healthcare provider's dosing instructions.

If your pharmacist offers to substitute another brand of TAC or generic TAC, please call your healthcare provider and/or Transplant Coordinator right away.

If you have a doctor's appointment with your family doctor or a health-care provider outside the transplant center, tell him or her you are taking ENVARSUS XR, and that it is not interchangeable with other TAC products.

Tell your healthcare proivder if you have any side effect that bothers you or that does not go away. The side effects listed in this guide are not all the possible side effects of ENVARSUS XR. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects.

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

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.

# What are the possible side effects of 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 healthcare provider right away if you have symptoms of an infection such as:

fever

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

**High blood sugar (diabetes).** Your healthcare provider may do certain tests to check for diabetes while you take ENVARSUS XR.

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

The most common side effects of ENVARSUS XR include, diarrhea, urinary tract infection, low red blood cell count (anemia), high blood pressure, and constipation.





# 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.

# Call your healthcare provider right away if you have symptoms of an infection such as:

fever

sweats or chills

• muscle aches

- warm, red, or painful areas on your skin
- cough or flu-like symptoms

#### 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, tacrolimus immediate-release capsules or tacrolimus for oral suspension. Your healthcare provider 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 healthcare provider before taking ENVARSUS XR? Before you take ENVARSUS 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. ENVARSUS XR may harm your unborn baby.
  - 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.
- are breastfeeding or plan to breastfeed. ENVARSUS XR passes into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking ENVARSUS XR.

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.

#### How should I take ENVARSUS XR?

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

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

Take ENVARSUS XR once daily with fluid (preferably water) on an empty, at least 1 hour before or at least 2 hours after a meal, stomach at the same time each day (preferably in the morning).

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

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 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 ENVARSUS XR, call your healthcare provider 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.

10

# Important Safety Information

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?**"

Problem 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.

- 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 ENVARSUS XR should look like.

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

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

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

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

- confusion
- numbness and tingling
- vision changes
- 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 ENVARSUS XR.

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

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

Severe low blood cell count (anemia)

The most common side effects of ENVARSUS 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 ENVARSUS 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 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 healthcare provider. You can ask your pharmacist or healthcare provider 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, butvlated 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.

12 13

# Our commitment to helping kidney transplant patients

Veloxis is dedicated to ensuring that all patients, regardless of their situation, receive their medication. Whether you have commercial or government insurance, or are uninsured/underinsured, we have dedicated financial support for patients taking ENVARSUS XR.

# 30-day Free Trial\*

Ask your healthcare provider. Start on ENVARSUS XR immediately, at no cost to you

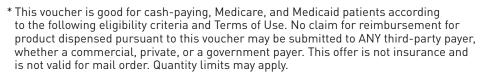
# \$0 Co-pay<sup>†</sup>

Out-of-pocket savings for eligible commercially insured patients

# Patient Assistance Program<sup>‡</sup>

Provides free medication for eligible patients

For more information on savings and support, please visit **www.EnvarsusXR.com** 



- <sup>†</sup> Eligible insured patients can save up to a maximum benefit of \$5,000 annually off the patient's co-pay or out-of-pocket expenses of ENVARSUS XR. Patient is responsible for any differential over \$5,000. This offer can be used an unlimited number of times. Offer not valid for cash paying patients or where drug is not covered by the primary insurance. This offer is valid in the United States. No substitutions permitted. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, Tricare, or other federal or state health programs (such as medical assistance programs).
- <sup>‡</sup> Please call your Specialist to see if your patient will qualify for Patient Assistance (free medication). This offer is not insurance and is not valid for mail order. Quantity limits may apply.



# Personalized post-transplant support

Veloxis Transplant Support offers dedicated support from Specialists who can confirm coverage and identify options for financial assistance. The Specialist is your single point of contact, who can help with:

# **Benefit Investigation**

Verifying coverage, identifying possible restrictions, and reporting cost sharing by tier

#### **Prior Authorization Assistance**

Guiding you through every step of a payer's process, identifying requirements, and providing templates for your healthcare provider's statements of medical necessity

# **Alternative Funding Research**

Identifying independent foundations that can assist patients who are underinsured or uninsured

# **Coordination With Specialty Pharmacies**

Ensuring access to ENVARSUS XR prior to filling prescription



# Veloxis | Transplant Support

1-844 VELOXIS (835-6947)

Monday-Friday, 9AM-7PM ET **VeloxisTransplantSupport.com** 

Veloxis is dedicated to ensuring that all patients, regardless of their situation, receive their medication.

www.EnvarsusXR.com



#### **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 healthcare provider about your medical condition or your treatment. If you have any questions about ENVARSUS XR, ask your healthcare provider 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:

fever
 cough or flu-like symptoms
 muscle aches
 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, tacrolimus [immediate-release] capsules or tacrolimus for oral suspension. Your healthcare provider 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 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. ENVARSUS 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 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.
  - There is a pregnancy registry for females who become pregnant and males who have fathered a pregnancy during treatment with ENVARSUS 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. ENVARSUS XR passes into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking ENVARSUS XR

**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.

#### How should I take ENVARSUS XR?

- Take ENVARSUS XR exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose of ENVARSUS XR if needed. Do not stop taking or change your dose of ENVARSUS XR without talking to your healthcare provider.
- Take ENVARSUS 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 ENVARSUS XR tablets whole. Do not chew, divide, crush, or dissolve ENVARSUS XR tablets before swallowing. If you cannot swallow ENVARSUS XR tablets whole, tell your healthcare provider.
- 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 healthcare provider 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?"
- 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.
  - o 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 ENVARSUS XR should look like.
- High blood sugar (diabetes). Your healthcare provider may do certain tests to check for diabetes while you take ENVARSUS XR. Call your healthcare provider right away if you have:

frequent urination
 confusion
 increased thirst or hunger
 drowsiness
 blurred vision
 loss of appetite

o fruity smell on your breath nausea, vomiting, or stomach pain

- Kidney problems. Kidney problems are serious and common side effects of ENVARSUS XR. Your healthcare provider may do certain tests to check for kidney function while you take ENVARSUS XR.
- Nervous system problems. Nervous system problems are a serious and common side effect of ENVARSUS XR. Call your healthcare provider right away if you
  get any of these symptoms while taking ENVARSUS XR. These could be signs of serious nervous system problems:

o confusion o coma o seizures

o numbness and tinglingo headacheo vision changeso muscle tremors

- High levels of potassium in your blood. Your healthcare provider may do certain tests to check your potassium level while you take ENVARSUS XR.
- High blood pressure. Your healthcare provider will monitor your blood pressure while you take ENVARSUS XR.
- Changes in the electrical activity of your heart (QT prolongation).
- Severe low blood cell count (anemia)

The most common side effects of ENVARSUS 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 ENVARSUS 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 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 FNVARSUS 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 healthcare provider. You can ask your pharmacist or healthcare provider 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: December 2018