To reduce proteinuria in adults with primary IgAN who are at risk of their disease getting worse quickly



If you have ongoing proteinuria, you may be at risk of your IgA nephropathy getting worse.

So, move faster and talk to your doctor about VANRAFIA® (atrasentan) and if it could be right for you.

## **Approved Use**What is VANRAFIA?

VANRAFIA is a prescription medicine used to reduce protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN) who are at risk of their disease getting worse quickly. It is not known if VANRAFIA is safe and effective in children.

VANRAFIA is approved based on a reduction of proteinuria. Continued approval may require results from an ongoing study to determine whether VANRAFIA slows decline in kidney function.

#### **Important Safety Information**

What is the most important information I should know about VANRAFIA?

VANRAFIA can cause serious birth defects if taken during pregnancy. Females should not be pregnant when they start taking VANRAFIA, become pregnant during treatment, or for 2 weeks after stopping treatment. Females who can become pregnant should have a negative pregnancy test before starting VANRAFIA.

Please see additional Important Safety Information throughout and on pages 17-18.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide.

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## Living with IgAN may make you feel uncertain

## So we created this brochure to help you feel more prepared for the journey ahead.

Inside, you'll find important information about VANRAFIA® (atrasentan) as a possible treatment option for IgA nephropathy, also known as Berger's disease. You'll also learn about the Novartis Patient Support™ program to help you start, stay, and save on treatment.

#### When it comes to IgAN, it may be time to move a little faster

Ongoing elevated Even if you think There is more your IgAN is stable, proteinuria\* you can do (protein in your elevated levels of to reduce urine) may mean proteinuria\* can be vour elevated that your IgAN is an indicator of risk proteinuria.\* getting worse. in IgAN.

## Make your move and ask your doctor if VANRAFIA could be right for you.

\*Elevated proteinuria ≥1.5 g/g in adults with primary IgAN is generally considered a high risk for disease worsening quickly.

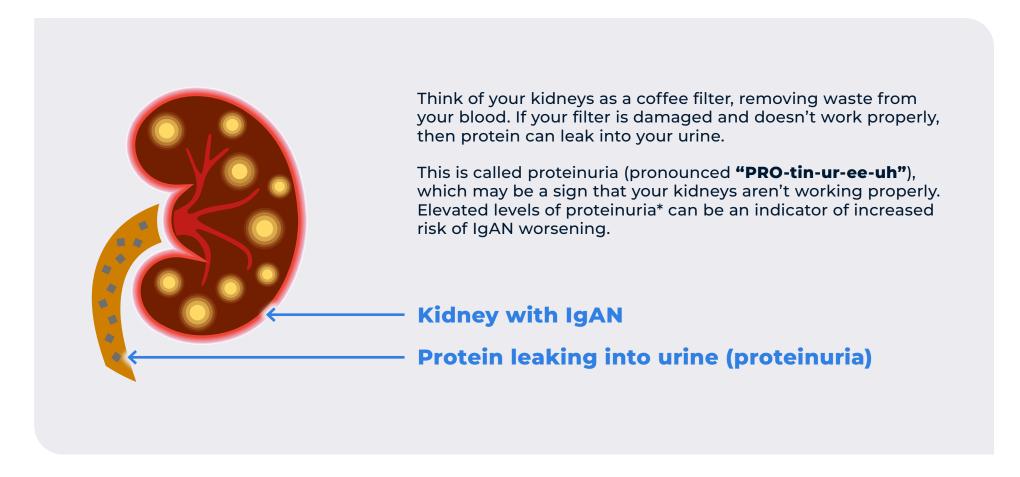
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# Elevated levels of protein in urine\* may be a sign that your IgA nephropathy is getting worse

IgAN is a long-lasting, progressive, autoimmune disease that results in an immune response to the formation of abnormal IgA protein. This can result in kidney damage.



<sup>\*</sup>Elevated proteinuria ≥1.5 g/g in adults with primary IgAN is generally considered a high risk for disease worsening quickly.

## Lower proteinuria is better

Ongoing elevated proteinuria\* is an important indicator that your IgAN may get worse.

According to expert guidelines for IgAN, proteinuria less than 1 g/day is an acceptable treatment goal.

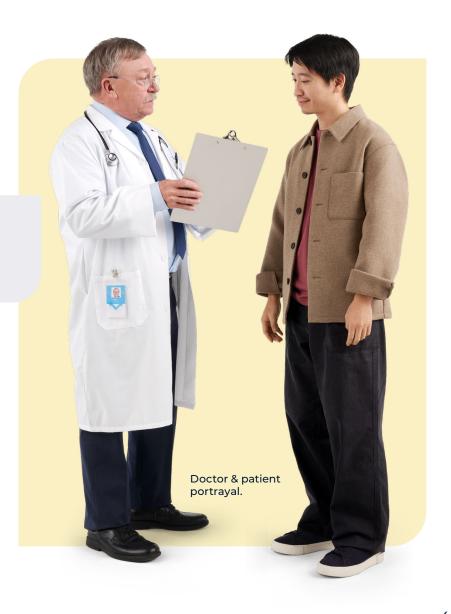
64% of people with IgAN still had ongoing proteinuria despite taking a blood pressure medication, like an ACEi or ARB, for 3 months.



**Track your lab numbers** so you can stay on top of your IgAN and have informed conversations with your doctor about how to treat it.

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.

\*Elevated proteinuria ≥1.5 g/g in adults with primary IgAN is generally considered a high risk for disease worsening quickly.



## VANRAFIA is approved for reducing proteinuria

#### In adults with IgAN who are at risk of their disease getting worse quickly

VANRAFIA is approved based on a reduction of proteinuria. Continued approval may require results from an ongoing study to determine whether VANRAFIA slows decline in kidney function.



Just one pill, once a day with or without food



An add-on to your current blood pressure medication\*



Designed to target the ET<sub>A</sub> pathway

Not a steroid

 $ET_A$ , endothelin type A.

\*Blood pressure medications include ACEi and ARB. VANRAFIA can also be added to a treatment prescribed to lower blood sugar, such as a sodium-glucose cotransporter-2 inhibitor (SGLT2i).

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#### Females who can become pregnant are those who:

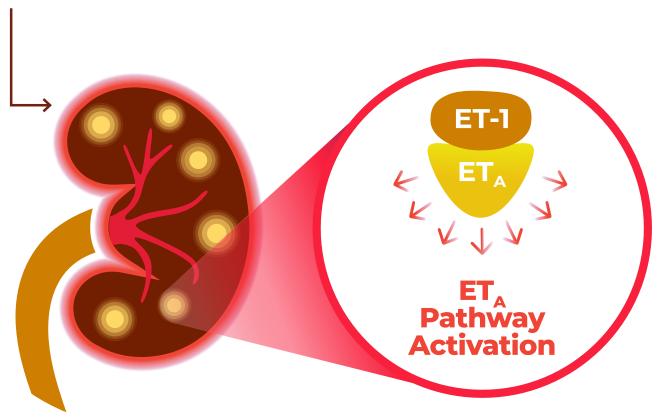
- Have entered puberty, even if they have not started their menstrual period, and
- Have a uterus, and
- Have not gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed.



# Activation of the $ET_A$ pathway is thought to contribute to IgAN

#### **Kidney with IgAN**

In IgAN, your immune system works against itself, activating a number of pathways, including the ET<sub>A</sub> pathway.



#### ET<sub>A</sub> pathway activation

In IgAN, production of ET-1 protein is increased. This increases activation of the  $ET_A$  pathway through  $ET_A$  receptors.

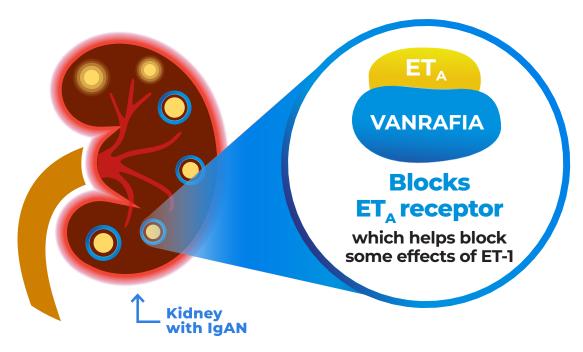
Activation of the  $ET_A$  pathway may lead to damaging effects in the kidneys, like inflammation.

ET<sub>A</sub>, endothelin type A.

### **VANRAFIA** is designed to target the ET<sub>A</sub> pathway

#### **VANRAFIA** in action

By blocking the ET<sub>A</sub> receptor, VANRAFIA is thought to block some effects of ET-1 in IgAN.



#### **Important Safety Information (continued)**

What is the most important information I should know about VANRAFIA? (continued)

#### Females who cannot become pregnant are those who:

- $\bullet$  Have not yet entered puberty,  ${\bf or}$
- Do not have a uterus, or
- Have gone through menopause. Menopause means that you have not had a menstrual period
  for at least 12 months for natural reasons, or that you have had your ovaries removed, or
- Are infertile for any other medical reason and this infertility is permanent and cannot be reversed.



# Studied in adults with IgAN as a once-daily add-on to current blood pressure medication\*

#### Who was studied?

A total of 340 adults with biopsy-proven IgAN who:



- had total urine protein ≥1 g/day
- were on a stable dose of maximally tolerated blood pressure medication, like ACEi or ARB

The initial results were based on the first **270 people** who reached the **9-month** visit who:

- had an average age of 45 years (19 to 77 years)
- were 59% male and 41% female, 57% Asian, 36% White, and 2% Black or African American

#### What was studied?



Of the 270 adults who reached the 9-month visit:

- 135 adults received 0.75 mg of VANRAFIA once daily in addition to blood pressure medication\*
   compared to
- 135 adults who received placebo (sugar pill) in addition to blood pressure medication\*

#### How was the study done?



Changes in protein in urine (proteinuria) were assessed using the urine protein-to-creatinine ratio (UPCR) test in urine samples collected over 24 hours at study initiation and through 9 months of treatment.

\*Participants were on a stable and maximally tolerated dose of a blood pressure medication, like ACEi or ARB.

#### **Important Safety Information (continued)**

What is the most important information I should know about VANRAFIA? (continued)

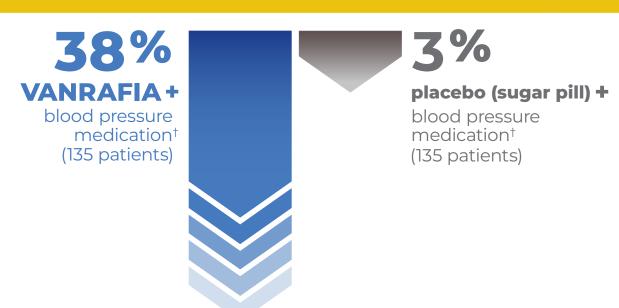
Females who can become pregnant should use effective birth control before starting treatment with VANRAFIA, during treatment with VANRAFIA, and for 2 weeks after stopping VANRAFIA because the medicine may still be in your body.



In adults with primary IgAN at risk of their disease getting worse quickly

# VANRAFIA substantially reduced proteinuria at 9 months

#### Reduction in proteinuria from start of the study\*



\*This study assessed urine protein levels using samples taken over 24 hours.

†Participants were on a stable and maximally tolerated dose of a blood pressure medication, like ACEi or ARB.

#### **Important Safety Information (continued)**

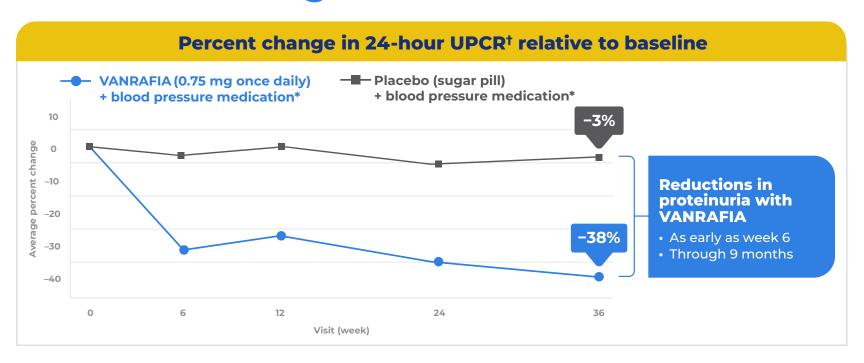
What is the most important information I should know about VANRAFIA? (continued)

Talk to your health care provider or gynecologist (a health care provider who specializes in reproduction) to find out about options for effective forms of birth control that you may use to prevent pregnancy during treatment with VANRAFIA.



As an add-on to a blood pressure medication\*

# Rapid and sustained proteinuria reduction with VANRAFIA through 9 months



UPCR, urine protein-to-creatinine ratio.

\*Participants were on a stable and maximally tolerated dose of a blood pressure medication, like ACEi or ARB. †This study assessed urine protein levels using samples taken over 24 hours.

#### **Important Safety Information (continued)**

What is the most important information I should know about VANRAFIA? (continued)

If you decide that you want to change the form of birth control that you use, talk to your health care provider or gynecologist to be sure that you choose another effective form of birth control.



### **Safety of VANRAFIA**

## Adverse reactions reported in ≥2% of adults treated with VANRAFIA and higher than placebo (sugar pill) in the clinical trial

Adverse Reaction	VANRAFIA (N=201)	Placebo (N=202)	These are not all of the possible side effects of VANRAFIA.
Swelling of hands, legs, ankles, and feet	10%	7%	Tell your doctor about any
Low red blood cells	6%	1%	side effect that bothers you or that does not go away.
Increased levels of liver enzymes	2%	1%	

#### For female patients with reproductive potential

VANRAFIA can cause serious birth defects if taken during pregnancy. Females should not be pregnant when they start taking VANRAFIA, become pregnant during treatment, or for 2 weeks after stopping treatment.

Do not take VANRAFIA if you are pregnant, plan to become pregnant, or become pregnant during treatment with VANRAFIA. VANRAFIA can cause serious birth defects. Do not take VANRAFIA if you are allergic to atrasentan or any of the ingredients in VANRAFIA.

- Talk to your health care provider or gynecologist (a health care provider who specializes in reproduction) to find out about options for effective forms of birth control that you may use to prevent pregnancy before, during and for two weeks after treatment with VANRAFIA
- Do not breastfeed during treatment with VANRAFIA

#### For male patients with reproductive potential

VANRAFIA, and other medicines like VANRAFIA, may cause decreased sperm counts in some men during treatment. A decreased sperm count may affect the ability to father a child. Tell your doctor if being able to have children is important to you.

• Decreased sperm counts were observed in some patients with diabetic kidney disease taking 0.75 mg of VANRAFIA once daily. These returned to normal levels within about 3 months after stopping the treatment. This effect has not been studied in people with IgAN

#### **Important Safety Information (continued)**

What is the most important information I should know about VANRAFIA? (continued)

**Do not have unprotected sex.** Talk to your health care provider or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your health care provider may talk to you about using emergency birth control.

Tell your health care provider right away if you miss a menstrual period or think you may be pregnant.

Please see additional Important Safety Information throughout and on pages 17-18. Please see full <u>Prescribing Information</u>, including Boxed WARNING and Medication Guide.



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### **VANRAFIA** can fit into your daily routine

#### Just one pill. Once a day.

VANRAFIA is an add-on to your current blood pressure medication, like an ACEi or ARB.

#### VANRAFIA is not a steroid.





Take once a day with or without food.



Swallow the tablets whole.



Do not cut, crush, or chew tablets.

If a dose or doses are missed, take the prescribed dose at the next scheduled time. The dose should not be doubled to make up for a missed dose.

#### **Important Safety Information (continued)**

Who should not take VANRAFIA?

#### Do not take VANRAFIA if you are:

- Pregnant, plan to become pregnant, or become pregnant during treatment with VANRAFIA. VANRAFIA can cause serious birth defects.
- Allergic to atrasentan or any of the ingredients in VANRAFIA.

#### Before taking VANRAFIA, tell your health care provider about all your medical conditions, including if you:

- Have liver problems.
- Are pregnant or plan to become pregnant during VANRAFIA treatment. VANRAFIA can cause serious birth defects.
- Are breastfeeding or plan to breastfeed. It is not known if VANRAFIA passes into your breast milk. Do not breastfeed during treatment with VANRAFIA. Talk to your health care provider about the best way to feed your baby if you take VANRAFIA.

**Tell your health care provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking VANRAFIA with certain medications may affect the way VANRAFIA, and the other medicine works and may increase your risk for side effects.

Do not start any new medicine until you check with your health care provider.



## No need to enroll in an FDA-required REMS\* monitoring program when starting treatment

Before beginning treatment with VANRAFIA, your doctor will order a liver enzyme and pregnancy test. Your doctor may decide to order follow-up testing during treatment.

Do not take VANRAFIA if you are pregnant, plan to become pregnant, or become pregnant during treatment with VANRAFIA. Do not take VANRAFIA if you are allergic to atrasentan or any of the ingredients in VANRAFIA.

VANRAFIA can cause serious birth defects if taken during pregnancy. Females should not be pregnant when they start taking VANRAFIA, become pregnant during treatment, or for 2 weeks after stopping treatment. Females who can become pregnant should have a negative pregnancy test before starting VANRAFIA.

Talk to your health care provider to find out about options for effective forms of birth control that you may use to prevent pregnancy before, during and for two weeks after treatment with VANRAFIA. Please see the Medication Guide for additional important safety information about VANRAFIA.



\*Risk Evaluation and Mitigation Strategy.

#### **Important Safety Information (continued)**

What are the possible side effects of VANRAFIA?

#### **VANRAFIA** may cause serious side effects, including:

- · Serious birth defects.
- Liver problems. Medicines like VANRAFIA can cause liver problems, including liver failure. VANRAFIA can increase liver enzymes in your blood. Your health care provider will do blood tests to check your liver enzymes before starting treatment and if needed during treatment. Your health care provider may temporarily stop or permanently stop treatment with VANRAFIA if your liver enzymes increase or if you develop symptoms of liver problems. Tell your health care provider if you have any of the following symptoms of liver problems while taking VANRAFIA:
  - Nausea or vomiting

Loss of appetite

Fever

- o Pain in the upper right stomach
- Yellowing of your skin or whites of your eyes
- Itching

Tiredness

Dark urine



## Join the IgAN patient community

#### There are several organizations dedicated to helping and connecting patients like you.\*

#### **IgAN.org**

**The IgA Nephropathy Foundation** is a network for advocacy and support run by patients, for patients.

#### **KidneyFund.org**

**The American Kidney Fund** is there for you at every stage of kidney disease—whether you're recently diagnosed or exploring treatment options.

Visit VANRAFIA on Facebook and Instagram for updates, treatment and disease information, and more.



facebook.com/ vanrafia.atrasentan

**NephCure.org** 

their own journeys.

right tools, resources, and care.



No matter where you are in your journey, NephCure

Share your story with the community

Email us at info@voices-of-inspiration.com to

help others find support and inspiration along

is there to support you, and connect you with the

<u>@vanrafia.</u> atrasentan

\*The organizations and websites listed on this page are maintained by third parties over which Novartis Pharmaceuticals Corporation has no control. As such, Novartis Pharmaceuticals Corporation makes no representation as to the accuracy or any other aspect of the information supplied by these organizations or contained in these websites.

#### **Important Safety Information (continued)**

What are the possible side effects of VANRAFIA? (continued)

 Fluid retention. VANRAFIA can cause your body to hold too much water. Tell your health care provider if you develop any unusual weight gain, trouble breathing, or swelling of your ankles or legs during treatment. Your health care provider may prescribe other medicines (diuretics) and may temporarily stop VANRAFIA if you develop fluid retention.



## **Novartis Patient Support™**

#### Personalized assistance that can help you start, stay, and save on treatment.

Once you and your health care provider decide to start you on VANRAFIA, you can sign up for Novartis Patient Support.

#### You have a dedicated team in your corner that can help with:



#### **Insurance support**

Your Novartis Patient Support team will work with your provider and health plan. They'll help navigate the insurance process, including when questions pop up.



#### **Financial support**

Your Novartis Patient Support team can keep you informed about potential offers. This includes the Co-Pay Plus offer and the VANRAFIA Bridge Program.



#### **Ongoing support**

Your Novartis Patient Support team can help answer your VANRAFIA questions and send you helpful resources when you need them.

### Sign up for **Novartis Patient** Support

There are a few different ways to start getting support:



#### Call 1-844-4VANRAF (1-844-482-6723),

Monday-Friday, 8:00 AM to 8:00 PM ET. excluding holidays. Your **Novartis Patient Support** Program team can help sign you up.



Sign up online by visiting support. **VANRAFIA.com** 



Ask your health care **provider** and/or their office staff to help you sign up for Novartis Patient Support.

#### **Important Safety Information (continued)**

About

What are the possible side effects of VANRAFIA? (continued)

• Decreased sperm count. VANRAFIA may cause decreased sperm counts in males and may affect the ability to father a child. Tell your health care provider if being able to have children is important to you.



## Sign up for Novartis Patient Support

There are a few different ways to start getting support:

## \$0 CO-PAY PLUS\* OFFER

Using your Co-Pay Plus offer: If you have private insurance, you may be eligible for a \$0 Co-Pay Plus offer for VANRAFIA through Novartis Patient Support.

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#### VANRAFIA BRIDGE PROGRAM\*

If you have private or commercial insurance, the VANRAFIA Bridge Program offers up to 12 months of VANRAFIA for free while we work with your health care provider and health insurance to help get your medication covered.

#### To enroll in the Co-Pay Plus\* program

Click here or call 1-844-4VANRAF (1-844-482-6723) to sign up.

#### **Terms and Conditions**

\*Limitations apply. Up to a \$15,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with private insurance and a prior authorization requirement or an initial denial of coverage may receive up to 12 months of free product while coverage is pursued. Novartis reserves the right to rescind, revoke, or amend this program without notice. Additional limitations may apply.

See complete Terms & Conditions at www.VANRAFIA.com for details.

#### **Important Safety Information (continued)**

#### The most common side effects of VANRAFIA include:

- Swelling of the hands, legs, ankles, and feet (peripheral edema)
- Low red blood cell count (anemia)

These are not all of the possible side effects of VANRAFIA. Call your health care provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.



### **Important Facts about VANRAFIA**

#### **Approved Use**

#### What is VANRAFIA?

VANRAFIA is a prescription medicine used to reduce protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN) who are at risk of their disease getting worse quickly. It is not known if VANRAFIA is safe and effective in children.

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#### Females who can become pregnant are those who:

- Have entered puberty, even if they have not started their menstrual period, and
- Have a uterus, and
- Have not gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed.

#### Females who cannot become pregnant are those who:

- Have not yet entered puberty, or
- Do not have a uterus, or
- Have gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed, **or**
- Are infertile for any other medical reason and this infertility is permanent and cannot be reversed.

Females who can become pregnant should use effective birth control before starting treatment with VANRAFIA, during treatment with VANRAFIA, and for 2 weeks after stopping VANRAFIA because the medicine may still be in your body.

Talk to your health care provider or gynecologist (a health care provider who specializes in reproduction) to find out about options for effective forms of birth control that you may use to prevent pregnancy during treatment with VANRAFIA.

If you decide that you want to change the form of birth control that you use, talk to your health care provider or gynecologist to be sure that you choose another effective form of birth control.

**Do not have unprotected sex.** Talk to your health care provider or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your health care provider may talk to you about using emergency birth control.

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#### **Important Safety Information (continued)**

#### Who should not take VANRAFIA?

#### Do not take VANRAFIA if you are:

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- Allergic to atrasentan or any of the ingredients in VANRAFIA.

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**Tell your health care provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking VANRAFIA with certain medications may affect the way VANRAFIA, and the other medicine works and may increase your risk for side effects. Do not start any new medicine until you check with your health care provider.

#### What are the possible side effects of VANRAFIA?

#### **VANRAFIA** may cause serious side effects, including:

- Serious birth defects.
- **Liver problems.** Medicines like VANRAFIA can cause liver problems, including liver failure. VANRAFIA can increase liver enzymes in your blood. Your health care provider will do blood tests to check your liver enzymes before starting treatment and if needed during treatment. Your health care provider may temporarily stop or permanently stop treatment with VANRAFIA if your liver enzymes increase or if you develop symptoms of liver problems. Tell your health care provider if you have any of the following symptoms of liver problems while taking VANRAFIA:
  - Nausea or vomiting
     Pain in the upper right stomach
     Tiredness
     Yellowing of your skin
     Dark urine
     Itching
     or whites of your eyes
     Fever
- Fluid retention. VANRAFIA can cause your body to hold too much water. Tell your health care provider if you develop any unusual weight gain, trouble breathing, or swelling of your ankles or legs during treatment. Your health care provider may prescribe other medicines (diuretics) and may temporarily stop VANRAFIA if you develop fluid retention.
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## It's time to make your move

#### Ask your doctor if VANRAFIA could be right for you.



### Just one pill, once a day, with or without food

As an add-on to blood pressure medications like an ACEi or ARB.



An IgAN therapy designed to target the ET<sub>A</sub> pathway

Not a steroid



Rapid and sustained reduction in proteinuria as early as Week 6 and sustained through 9 months

Reduction in proteinuria at 9 months: 38% with VANRAFIA

- + blood pressure medications vs 3% with placebo (sugar pill)
- + blood pressure medications\*

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## No need to enroll in an FDA-required REMS† monitoring program when starting treatment

Before beginning treatment with VANRAFIA, your doctor will order a liver enzyme and pregnancy test. Your doctor may decide to order follow-up testing during treatment.

Talk to your health care provider to find out about options for effective forms of birth control that you may use to prevent pregnancy during treatment with VANRAFIA. Please see the Medication Guide for additional important safety information about VANRAFIA.



The most common adverse reactions (≥5%) with VANRAFIA were: swelling of hands, legs, ankles, and feet and low red blood cells.

## **Approved Use**What is VANRAFIA?

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<sup>†</sup>Risk Evaluation and Mitigation Strategy.