

Getting started with VANRAFIA®

for the treatment of IgA nephropathy (IgAN) in adults with primary IgAN who are at risk of their disease getting worse quickly

IgAN, immunoglobulin A nephropathy.

Approved UseWhat 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.

Welcome to the start of your VANRAFIA® journey

We know that starting a new treatment can feel overwhelming. This brochure can help you on your way.

We want you to know what to expect as you get started with your treatment. We also want you to understand all of the resources that you can rely on at every step.

Keep this brochure handy. Refer to it when you have questions. And explore the personalized support options offered through Novartis Patient Support.

Here are some steps you can take to help get started:



NOVARTIS PATIENT SUPPORT TM Personalized assistance that can help you start, stay, and save on treatment
INSURANCE COVERAGE Work with your doctor to navigate the insurance process
SPECIALTY PHARMACY Work with your specialty pharmacy to receive VANRAFIA
TAKING VANRAFIA Start taking VANRAFIA as prescribed

Important Safety Information (continued)

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

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.



Novartis Patient Support™ can help you along the way

Once you and your health care provider decide to start VANRAFIA®, you can sign up for Novartis Patient Support. It's a personalized program designed to help you start, stay, and save on treatment.

You have a dedicated team in your corner to 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.

Ready for personalized support through Novartis Patient Support?

Click here or call 1-844-4VANRAF (1-844-482-6723), Monday–Friday, 8:00 AM to 8:00 PM ET, excluding holidays. Your Novartis Patient Support team can then help you sign up.



INSURANCE SUPPORT



VANRAFIA® and insurance coverage

As you prepare to get your first VANRAFIA prescription, we suggest you take some time to review this important information based on your individual insurance scenario.



What if my coverage is denied?

Denial of benefits may occur, but this can be appealed. An appeal is a request for your insurance company to reconsider its decision about denying coverage of your medication. Your doctor can submit an appeal letter to your insurer, usually along with important details about your condition.

You can also write a letter to go along with your doctor's appeal letter to explain why your claim should be accepted.

If you have commercial insurance, you may be able to start your treatment while your coverage is being pursued.

If eligible, the VANRAFIA Bridge Program* can help you receive your medication for free, for up to 12 months, when coverage is delayed or denied, while coverage is pursued. Once you receive the approval, you can start using your VANRAFIA \$0 Co-Pay Plus* offer to help cover your out-of-pocket costs.

What if I have limited or no prescription coverage and cannot afford my medication?

If you have questions about financial assistance or are not covered by health insurance, Novartis Patient Support can help by connecting you with the Novartis Patient Assistance Foundation (NPAF). NPAF is an independent 501(c)(3) non-profit organization that provides Novartis medications free of cost to eligible patients who have limited or no prescription insurance coverage and cannot afford the cost of their medication.

To be eligible, you must:

- Reside in the United States or a US territory
- Be treated by a licensed US health care provider on an outpatient basis
- Meet income and insurance guidelines

For additional information, **please visit PAP.Novartis.com or call NPAF at 1-800-277-2253.**To check eligibility and enroll in the NPAF, please ask your doctor to submit a Start Form to Novartis Patient Support.

VANRAFIA™
(atrasentan) tablets
0.75 mg

*See terms and conditions indicated on the next page.

Please see Important Safety Information throughout and on pages 10-11. Please see full Prescribing Information, including Boxed WARNING and Medication Guide.

\$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.

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)

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

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.



Here are some insurance terms you may encounter

Appeal

A request for your insurance company to reconsider its decision about denying coverage of your medication.

Benefits verification

This is when Novartis Patient Support or the specialty pharmacy checks your coverage with your insurer. The benefits verification process will confirm the next steps for obtaining approval for VANRAFIA®.

Co-Pay

A predetermined, fixed amount you pay for your medication after your health plan covers a portion of the total cost.

Coinsurance

The percentage of covered medical costs you'll pay after you've reached your deductible.

Deductible

The amount you pay for a prescription before your insurance starts to pay its portion of the cost.

Formulary

A list of prescription medications covered by a prescription medication plan or another insurance plan offering prescription medication benefits.

Government insurance

Insurance reserved for specific groups of people (eg, senior citizens, persons with low income, persons with disability, current military and their families, government employees, and some federally recognized Native American tribes) and funded by the government. Medicare, Medicaid, TRICARE, and the Veterans Health Administration program are all examples of government insurance.

Continued on the next page.





Out-of-pocket maximum

The most you will have to pay for prescription medication in a year. After you spend this amount on deductibles, co-pays, and coinsurance, your insurance plan covers 100% of the cost.

Patient support program

A program like Novartis Patient Support that helps patients, caregivers, and health care professionals find the right support when they need it.

Premium

The amount you pay for your health insurance every month.

Prior authorization

An approval given by your insurance company so your prescription is covered by your plan.

Private insurance (sometimes called commercial insurance)

Insurance you buy individually or through your employer.

Retail pharmacy

An independent or chain pharmacy that dispenses medication to the general public at retail prices.

Specialty pharmacy

A pharmacy that carries medications that require specific handling and storage.

Step therapy

A process by which insurers (public or private) require patients to take one or more alternative medications before they can access the medicine prescribed by their provider.



Receive VANRAFIA® from a specialty pharmacy

VANRAFIA is only available through select specialty pharmacies that will deliver it to your door each month.



CareMed*

Website: <u>caremedsp.com</u> Main phone: 1-877-227-3405



Biologics

Website: <u>biologics.mckesson.com</u> Main phone: 1-800-850-4306

*CareMed is a subsidiary of Onco360®.

Steps to receive VANRAFIA:



VANRAFIA arrives at your doorstep.

If you have not heard anything regarding your prescription and would like an update, you can also contact your doctor or the Specialty Pharmacy directly.

You speak to the specialty pharmacy.

The specialty pharmacy cannot ship you VANRAFIA until they have spoken with you on a live call. They may call from a number you don't recognize, so please be ready to pick up the phone or call them back.

If you have not heard from your specialty pharmacy for a refill reminder, call your doctor or your pharmacy as soon as possible.





Just one pill. Once a day.

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



Taking your medication:

- Take one tablet once a day with or without food
- Swallow the tablets whole
- Do not cut, crush, or chew tablets
- Each tablet contains 0.75 mg of VANRAFIA



If you miss a dose or doses of VANRAFIA:

take the prescribed dose of VANRAFIA at the next scheduled time. The dose should not be doubled to make up for a missed dose.



Staying on treatment is important

To help incorporate VANRAFIA into your daily routine, try to take it when doing another daily activity like brushing your teeth or eating breakfast.



Set up reminders to keep on track with your medication:

- Use your smartphone to set alarms
- Add reminders to your calendar
- Place a pillbox in obvious, easy-to-remember places
- Sign up for a medication reminder program or app

Take VANRAFIA exactly as your doctor tells you. Do not change the dose or stop taking VANRAFIA unless your doctor tells you.

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.

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker. *Risk Evaluation and Mitigation Strategy.

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.



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.

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

Continued on the next page.



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.

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

Dark urine

Pain in the upper right stomach

Yellowing of your skin

Fever

Tiredness

or whites of your eyes

Itching

- 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.
- **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.

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.



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

More ways to connect and learn



Stay connected to VANRAFIA®

Sign up now at VANRAFIA.com to receive email updates and important information.



Join the IgAN patient community

Having IgAN can make you feel isolated, but there are organizations dedicated to helping patients like you. Check out The IgA Nephropathy Foundation at IgAN.org, NephCure.org, and The American Kidney Fund at kidneyfund.org.*



Want to share your VANRAFIA story?

Help inspire and empower other patients with IgAN by sharing your experiences. Call 1-877-879-0245 (8 AM to 5 PM PT) or email info@voices-of-inspiration.com.



Learn more about VANRAFIA

VANRAFIA.com is your first stop for everything VANRAFIA, with resources to help you understand your treatment and more.



And remember:

you can always visit VANRAFIA.com for more information and support.

*The organizations and websites listed 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.



