

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **VANRAFIA**[™]

Atrasentan Tablets

This Patient Medication Information is written for the person who will be taking **VANRAFIA**[™]. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **VANRAFIA**, talk to a healthcare professional.

Serious warnings and precautions box

Pregnancy: VANRAFIA may cause major birth defects or even death of an unborn baby when used in pregnant women. Do **not** take VANRAFIA if you are pregnant. Your healthcare professional will advise on the potential risks to your unborn baby.

If you are a female who is able to get pregnant:

- A pregnancy test will be done before you start your treatment with VANRAFIA to show that you are not pregnant.
- Pregnancy tests are required monthly during treatment and one month after stopping your treatment with VANRAFIA.
- You should use a reliable form of birth control before, during, and at least one month after stopping your treatment with VANRAFIA. Talk to your healthcare professional about your options.

If you become pregnant or think that you may be pregnant while taking VANRAFIA, or up to one month after stopping VANRAFIA, talk to your healthcare professional immediately and stop taking VANRAFIA.

What VANRAFIA is used for:

VANRAFIA is used to treat adults with immunoglobulin A nephropathy (IgAN), a kidney disease.

How VANRAFIA works:

VANRAFIA belongs to a group of medicines known as endothelin receptor antagonists (ERAs). It works by blocking the harmful effects of a chemical called endothelin. Endothelin becomes overactive in patients with IgAN, often causing inflammation, protein in the urine, and a decline in kidney function over time. By blocking endothelin, VANRAFIA helps to reduce protein levels in the urine and may stabilize kidney function.

The ingredients in VANRAFIA are:

Medicinal ingredient(s): atrasentan hydrochloride.

Non-medicinal ingredients: crospovidone, glyceryl dibehenate, hypromellose, lactose monohydrate, L-cysteine hydrochloride monohydrate, polyethylene glycol, and silicon dioxide.

VANRAFIA comes in the following dosage form(s):

Film-coated tablets: 0.75 mg of atrasentan (as atrasentan hydrochloride).

The film-coated tablets are round, biconvex, white to off-white tablets marked with “7” on one side and unmarked on the other side.

Do not use VANRAFIA if:

- you are pregnant, plan to become pregnant, or become pregnant during treatment with VANRAFIA. VANRAFIA may harm the unborn baby. See the “**Serious warnings and precautions box**” above for more information.
- you are allergic to atrasentan or any of the other ingredients of VANRAFIA. See the “The ingredients in VANRAFIA are” above.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VANRAFIA. Talk about any health conditions or problems you may have, including if you:

- are breastfeeding or plan to breastfeed. It is not known if VANRAFIA passes into your breast milk. Do not breastfeed while you are taking VANRAFIA.
- have notice an accumulation of fluid in your body (fluid retention).
- have liver problems.
- are a women who can become pregnant. See the “**Serious warnings and precautions box**” above for more information.
- are lactose intolerant. VANRAFIA contains a lactose component.

Other warnings you should know about:

- **Fertility:** A decrease in sperm counts has been observed in some male patients after taking VANRAFIA. Talk to your healthcare professional if you have any questions or concerns about this.
- **Testing and check-ups:** Your healthcare professional will regularly monitor your health before, during, and after your treatment with VANRAFIA. Depending on your results, your healthcare professional may adjust or stop your treatment as needed. This includes monitoring:
 - your liver,
 - your weight and for swelling, and
 - if you are pregnant.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VANRAFIA:

- Cyclosporine used to suppress the immune system and prevent transplant rejection, or other medicines known as OATP1B1/1B3 inhibitors.
- Ketoconazole used to treat fungal infections, or other medicines known as strong CYP3A inhibitors.
- Rifampicin used to treat bacterial infections, or other medicines known as strong CYP3A inducers.
- Efavirenz used to treat HIV infections, or other medicines known as moderate CYP3A4 inducers.

If you are unsure, ask your healthcare professional. You should also tell your healthcare professional if you have recently taken or plan to take any other medicines. This includes medicines obtained without a prescription.

How to take VANRAFIA:

- Always take VANRAFIA exactly as your healthcare professional tells you. Do not change your dose or stop taking unless your healthcare provider tells you to. If you have any questions, talk to your healthcare professional.
- Swallow the VANRAFIA tablet whole with or without food. Do **not** crush or chew the tablet.
- Continue taking VANRAFIA every day for as long as your healthcare professional tells you.

Usual dose:

Your healthcare professional will decide the right dose and frequency of VANRAFIA for you. The usual dose of VANRAFIA is 0.75 mg once daily.

Overdose:

If you take more VANRAFIA than prescribed, you may have a headache, feel lightheaded, or feel dizzy.

If you think you, or a person you are caring for, have taken too much VANRAFIA, contact a healthcare professional, hospital emergency department, regional poison control centre, or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss or forget to take a dose, skip the missed dose and then take the next dose at the usual scheduled time. Do **not** take a double dose to make up for a missed or forgotten dose.

Possible side effects from using VANRAFIA:

These are not all the possible side effects you may have when taking VANRAFIA. If you experience any side effects not listed here, tell your healthcare professional.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Peripheral edema (swelling of the legs or hands caused by fluid retention): swollen/puffy legs or hands, or feeling heavy, achy, or stiff.		X	
Common			
Anemia (low red blood cell levels): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, or weakness.		X	
Hypotension (low blood pressure): dizziness, fainting, feeling lightheaded, blurred vision, nausea, vomiting, or fatigue (may occur when you go from lying or sitting to standing up).		X	
Liver problems: nausea, vomiting, right upper abdominal pain, fatigue, fever, joint pain, muscle pain, weight loss, yellowing of the skin or white portion of the eyes, or dark urine.		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store VANRAFIA between 15°C to 25°C.
- Do **not** take VANRAFIA after the expiration date or 35 days after first opening the bottle, whichever comes first.
- Keep this medicine out of reach and sight of children.

If you want more information about VANRAFIA:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.novartis.ca), or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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