

MEDICATION GUIDE
VANRAFIA™ (van-rah-fee-ah)
(atrasentan)
tablets

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 or become pregnant during treatment with VANRAFIA or for two weeks after stopping treatment with VANRAFIA.**
- Females who can become pregnant should have a negative pregnancy test before starting VANRAFIA.
 - 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 with your healthcare provider or gynecologist (a healthcare 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 with your healthcare provider or gynecologist to be sure that you choose another effective form of birth control.
- **Do not have unprotected sex.** Talk to your healthcare provider or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your healthcare provider may talk with you about using emergency birth control.
- **Tell your healthcare provider right away if you miss a menstrual period or think you may be pregnant.** See **“What are the possible side effects of VANRAFIA?”** for more information about side effects.

What is VANRAFIA?

VANRAFIA is a prescription medicine used to reduce levels of 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.

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. See “What is the most important information I should know about VANRAFIA?”**
- **allergic to atrasentan** or any of the ingredients in VANRAFIA. See the end of this Medication Guide for a complete list of ingredients in VANRAFIA.

Before taking VANRAFIA, tell your healthcare 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. See **“What is the most important information I should know about VANRAFIA?”**
- 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 with your healthcare provider about the best way to feed your baby if you take VANRAFIA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking VANRAFIA with certain other medicines 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 healthcare provider.

How should I take VANRAFIA?

- Take VANRAFIA exactly as your healthcare provider tells you. Do not change your dose or stop taking unless your healthcare provider tells you to.
- Take 1 VANRAFIA tablet 1 time each day with or without food.
- Swallow VANRAFIA tablets whole. Do not cut, crush, or chew VANRAFIA tablets.
- If you miss a dose or more doses of VANRAFIA, skip the missed dose and take your next dose at your regularly scheduled time. Do not take 2 doses at the same time to make up for a missed dose.
- If you take too much VANRAFIA, call your healthcare provider right away or go to the nearest hospital or emergency room.

What are the possible side effects of VANRAFIA?

VANRAFIA can cause serious side effects, including:

- **Serious birth defects.** See **"What is the most important information I should know about VANRAFIA?"**
- **Liver problems.** Medicines like VANRAFIA can cause liver problems, including liver failure. VANRAFIA can increase liver enzymes in your blood. Your healthcare provider will do blood tests to check your liver enzymes before starting treatment and if needed during treatment. Your healthcare 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 healthcare provider if you develop any of the following symptoms of liver problems during treatment with VANRAFIA.
 - nausea or vomiting
 - pain in the upper right stomach
 - tiredness
 - loss of appetite
 - yellowing of your skin or whites of your eyes
 - dark urine
 - fever
 - itching
- **Fluid retention.** VANRAFIA can cause your body to hold too much water. Tell your healthcare provider if you develop any unusual weight gain, trouble breathing, or swelling of your ankles or legs during treatment. Your healthcare 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 healthcare provider if being able to have children is important to you.

The most common side effects of VANRAFIA include:

- swelling of hands, legs, ankles, and feet (peripheral edema)
- low red blood cells (anemia)

These are not all of the possible side effects of VANRAFIA. 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 VANRAFIA?

- Store VANRAFIA at room temperature between 68°F to 77°F (20°C to 25°C).
- Store VANRAFIA in the original container.
- The bottle has a child-resistant cap and contains a desiccant to help keep the tablets dry.

Keep VANRAFIA and all medicines out of the reach of children.

General information about the safe and effective use of VANRAFIA

Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide. Do not use VANRAFIA for a condition for which it was not prescribed. Do not give VANRAFIA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about VANRAFIA that is written for health professionals.

What are the ingredients in VANRAFIA?

Active ingredient: atrasentan

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

Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936

© 2025 Novartis

For more information, go to www.VANRAFIA.com or call 1-888-669-6682.