



*You've Got This*

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Please see Important Safety Information for RUKOBIA throughout  
this brochure and Important Facts about RUKOBIA on pages 9-10.



"It's important to stay resilient and hopeful."

-Dennis

is taking RUKOBIA as part of an HIV-1 regimen.

## What is RUKOBIA?

RUKOBIA is a prescription medicine used with other antiretroviral (ARV) medicines to treat HIV-1 in adults who:

- have received several anti-HIV-1 regimens in the past, **and**
- have HIV-1 virus that is resistant to many ARV medicines, **and**
- are failing their current ARV therapy because it is not working, are not able to tolerate the side effects, or have other safety concerns.

HIV-1=human immunodeficiency virus type 1.

## About RUKOBIA

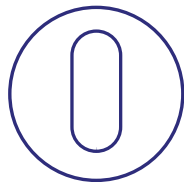
RUKOBIA is an HIV-1 treatment that works differently from other HIV-1 treatments by stopping the virus from attaching to your CD4<sup>+</sup> T-cells.

RUKOBIA is not for use alone. RUKOBIA will be given along with an HIV-1 treatment regimen recommended by your doctor.

RUKOBIA is proven to help decrease viral load in some people whose virus is still detectable despite having exhausted many other treatment options.\*

\*Results may vary.

## How do I take RUKOBIA?



**One 600-mg tablet**  
Tablet shown is not actual size



**Taken twice daily around the same time each day**



**With or without food**

- Swallow tablets whole. Do not chew, crush, or split tablets

2 Please see Important Safety Information for RUKOBIA throughout this brochure and Important Facts about RUKOBIA on pages 9-10.

## IMPORTANT SAFETY INFORMATION

**Do not take RUKOBIA if you:**

- **are allergic** to fostemsavir or any of the ingredients in RUKOBIA.
- **take certain medicines, including** enzalutamide, carbamazepine, phenytoin, rifampin, mitotane, St. John's wort (*Hypericum perforatum*).

**What are the possible side effects of RUKOBIA?**

**RUKOBIA can cause serious side effects including:**

- **Changes in your immune system.** Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after you start taking RUKOBIA.



## How RUKOBIA was studied

In a clinical study of 371 adults with HIV-1, RUKOBIA was added to a treatment regimen and evaluated at Day 8, Weeks 24, 96, and 240.

People who entered the study met the following criteria:

**The virus was detectable while on their current regimen**  
(viral load greater than or equal to 400 copies/mL)

**The virus was resistant to many HIV-1 treatments**

**They had limited treatment options**  
(no more than 2 antiretroviral classes remaining)

## The study included people with advanced HIV-1:

- 89% had viral load greater than 1000 copies/mL
- 75% had CD4<sup>+</sup> T-cells\* less than 200 cells/mm<sup>3</sup>
- 86% had history of AIDS
- 30% had CD4<sup>+</sup> T-cells less than 20 cells/mm<sup>3</sup>

\*CD4<sup>+</sup> T-cells (also called T-cells) are white blood cells that help fight infections. CD4<sup>+</sup> T-cell count is the number of CD4<sup>+</sup> T-cells per mm<sup>3</sup> of blood.

AIDS=acquired immune deficiency syndrome.



To hear that there was another medication being worked on out there somewhere that could possibly benefit me, I was extremely happy.

*-Dennis* Taking RUKOBIA as part of an HIV-1 regimen.

## IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of RUKOBIA? (cont'd)

RUKOBIA can cause serious side effects including: (cont'd)

- **Heart rhythm problems (QTc prolongation).** RUKOBIA may cause a heart rhythm problem called QTc prolongation. QTc prolongation causes an irregular heartbeat. If you are elderly, you may be at a greater risk for developing this heart problem with RUKOBIA. **Tell your healthcare provider right away** if you feel dizzy, lightheaded, feel changes in your heartbeat, or you faint (lose consciousness).
- **Changes in liver function blood tests results.** People with HIV-1 who take RUKOBIA and who also have hepatitis B or C virus infections, may be more likely to develop new or worsening changes in certain liver function blood tests during treatment with RUKOBIA.
  - If you stop your anti-hepatitis B treatment, this could mean that your hepatitis B may become active again (reactivated). Your healthcare provider may do blood tests to check your liver function.
  - Take any anti-hepatitis B or anti-hepatitis C medicines as prescribed by your healthcare provider during treatment with RUKOBIA.

## Viral load decreased after 8 days\*

During the first 8 days of the study, people were randomly selected to receive either RUKOBIA or a sugar pill added to their current regimen. After 8 days, the average viral load decrease was evaluated.

	RUKOBIA + CURRENT REGIMEN	SUGAR PILL + CURRENT REGIMEN
Number of people	201	69
Average viral load decrease†	↓ 84%	↓ 32%

At Day 9, all people still on their current regimen were changed to RUKOBIA along with a tailored treatment regimen‡ for the remainder of the study.

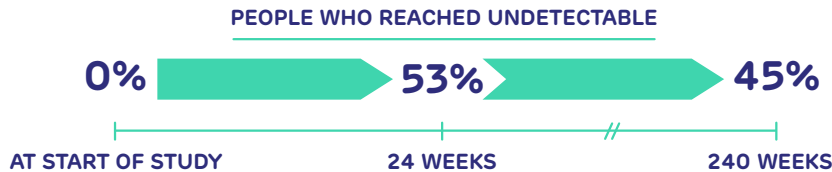
\*Results may vary.

†Calculated from viral load changes:  $-0.79 \log_{10}$  (RUKOBIA + current regimen) and  $-0.17 \log_{10}$  (sugar pill + current regimen).

‡The tailored treatment regimen was based on the needs of each person and the number of active antiretroviral therapies remaining to replace their current regimen.

## Some people reached undetectable and remained undetectable at 240 weeks<sup>§</sup>

More than half of the 272 people who took RUKOBIA with a tailored treatment regimen reached undetectable by 24 weeks and some continued to remain undetectable at 240 weeks.



- Undetectable means reducing the HIV in your blood to very low levels
- In the study, undetectable was defined as less than 40 copies/mL

**RUKOBIA, in conjunction with the other antiretrovirals I'm taking, got me to undetectable. And I've stayed there.<sup>§</sup>**

*-Dennis* Taking RUKOBIA as part of an HIV-1 regimen.

<sup>§</sup>Results may vary.

## IMPORTANT SAFETY INFORMATION (cont'd)

**The most common side effect of RUKOBIA is nausea.**

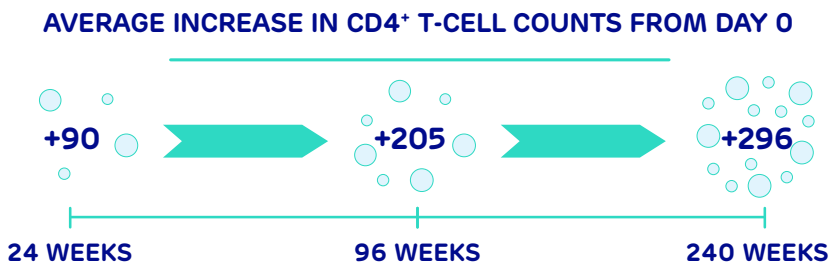
These are not all of the possible side effects of RUKOBIA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**Before taking RUKOBIA, tell your healthcare provider about all of your medical conditions, including if you:**

- have or have had a heart problem, including a heart rhythm problem called QTc prolongation (irregular heartbeat).
- have or have had liver problems, including hepatitis B or C infection.
- are pregnant or plan to become pregnant. It is not known if RUKOBIA will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with RUKOBIA.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take RUKOBIA.** You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

## Increased CD4<sup>+</sup> T-cell counts\*†

As part of a tailored treatment regimen,‡ RUKOBIA increased and maintained the number of infection-fighting CD4<sup>+</sup> T-cells in the immune system.



- In people with a low CD4<sup>+</sup> T-cell count (below 20 cells/mm<sup>3</sup>) at the start of the study, RUKOBIA, added to a tailored treatment regimen, helped increase CD4<sup>+</sup> T-cells by more than 200 cells/mm<sup>3</sup> on average

\*Results may vary.

†CD4<sup>+</sup> T-cells (also called T-cells) are white blood cells that help fight infections. CD4<sup>+</sup> T-cell count is the number of CD4<sup>+</sup> T-cells per mm<sup>3</sup> of blood.

‡The tailored treatment regimen was based on the needs of each person and the number of active antiretroviral therapies remaining to replace their current regimen.

## What were the most common side effects?§

The most common side effect through 240 weeks, reported by 5% or more of people, was nausea (11%).

- 8% of people stopped taking RUKOBIA because of adverse events

## What are the possible side effects of RUKOBIA?

RUKOBIA can cause serious side effects including:

- changes in your immune system (Immune Reconstitution Syndrome)
- heart rhythm problems (QTc prolongation)
- changes in liver function blood tests results

These are not all the possible side effects of RUKOBIA. Always tell your doctor if you experience any side effects.

§Results may vary.

## IMPORTANT SAFETY INFORMATION (cont'd)

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with RUKOBIA.

**Especially tell your healthcare provider** if you take birth control pills (oral contraceptives) that contain ethinyl estradiol. The amount of ethinyl estradiol can become increased in your blood during treatment with RUKOBIA. Talk to your healthcare provider about which oral contraceptives may be right for you during treatment with RUKOBIA.



# Dennis's Story

## Dennis is taking RUKOBIA as part of an HIV-1 regimen

### Dennis, tell us a little bit about yourself.

My name is Dennis. I'm married. I live with my husband, our two rescue dogs, and a rescue cat. I'm a heavily treatment-experienced person living with HIV.

### What are some challenges you've experienced on your treatment journey?

When I started having treatment failure I'd say, "Oh. We're seeing virus again. But what's out there for me to take?" I had resistance to multiple classes of medications.

### How did you feel when you heard about RUKOBIA?

I remember hearing of this (RUKOBIA) and I was like, "Wow, we do matter."

### What did it feel like for you to hear that you reached undetectable status while taking RUKOBIA as part of your HIV-1 regimen?

Oh, I cheered. I cheered loud.

### What's something that helped you throughout your treatment journey?

The emotional support that you're getting from friends or family is important, because those are the people that can give you encouragement.

## IMPORTANT SAFETY INFORMATION (cont'd)

Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with RUKOBIA.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take RUKOBIA with other medicines.



*James* is living with HIV.

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When I speak to people who are living with HIV, I want them to realize that this is a lifetime journey—we gotta do what's necessary to take care of ourselves and others.

*-James*

For so long you think, 'It's just me. I'm here by myself.' And the reality is you were never by yourself.

*-James*

## IMPORTANT SAFETY INFORMATION (cont'd)

How should I take RUKOBIA?

- Take RUKOBIA exactly as your healthcare provider tells you to take it.
- Take RUKOBIA tablets whole. Do not chew, crush, or split RUKOBIA tablets before swallowing.
- Take RUKOBIA with or without food.

7 Please see Important Safety Information for RUKOBIA throughout this brochure and Important Facts about RUKOBIA on pages 9-10.



## Talking to your doctor about RUKOBIA

You may have questions about taking RUKOBIA or how it may fit into your daily life. It's important for your doctor to know your concerns so you can have a productive conversation.

Use these questions to keep the conversation going with your doctor about treatment with RUKOBIA—and get the answers you need.

### Questions to ask your doctor about RUKOBIA:

- How might RUKOBIA help me reach my health goals for living with HIV-1?
- Can RUKOBIA help me reach undetectable?
- Will RUKOBIA help increase my CD4+ T-cell count?
- What other HIV-1 medicines should I take with RUKOBIA?
- How do I take RUKOBIA? What should I do if I miss a dose?
- What are the possible side effects of RUKOBIA?
- Can RUKOBIA interact with the additional medicines I'm taking for other conditions?
- Where can I get support information for my RUKOBIA prescription?

## Notes

Use the space below to write down any questions or concerns you may have so you can share them with your doctor during office visits.

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## IMPORTANT SAFETY INFORMATION (cont'd)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Please read the Patient Information for RUKOBIA and discuss it with your healthcare provider.



The only way that you can have trust in your doctor is you gotta be willing to share where you are and what's going on with you.

*-James* Living with HIV.







(rue-KOH-bee-ah)

## IMPORTANT FACTS

This is only a brief summary of important information about RUKOBIA and does not replace talking to your healthcare provider about your condition and treatment.

### ABOUT RUKOBIA

RUKOBIA is a prescription medicine that is used with other antiretroviral medicines to treat Human Immunodeficiency Virus (HIV-1) infection in adults who:

- have received several anti-HIV-1 regimens in the past, **and**
- have HIV-1 virus that is resistant to many antiretroviral medicines, **and**
- are failing their current antiretroviral therapy. You could be failing therapy because it is not working or no longer works, you are not able to tolerate the side effects, or there are other safety reasons why you cannot take it.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

It is not known if RUKOBIA is safe and effective in children.

### HOW TO TAKE RUKOBIA

- **Take RUKOBIA 2 times a day exactly as your healthcare provider tells you to take it.**
- Take RUKOBIA tablets whole. Do not chew, crush, or split RUKOBIA tablets before swallowing.
- RUKOBIA can be taken with or without food.

### DO NOT TAKE RUKOBIA IF YOU

- **are allergic** to fostemsavir or any of the ingredients in RUKOBIA.
- **take certain medicines, including:** enzalutamide; rifampin; carbamazepine; mitotane; phenytoin; St. John's wort (*Hypericum perforatum*)

### BEFORE TAKING RUKOBIA

**Tell your healthcare provider about all of your medical conditions, including if you:**

- have or have had a heart problem, including a heart rhythm problem called QTc prolongation (irregular heartbeat).
- have or have had liver problems, including hepatitis B or C virus infection.
- are pregnant or plan to become pregnant. It is not known if RUKOBIA will harm your unborn baby.

Tell your healthcare provider if you become pregnant during treatment with RUKOBIA.

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take RUKOBIA.** You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. It is not known if RUKOBIA can pass to your baby in your breast milk. Talk with your healthcare provider about the best way to feed your baby during treatment with RUKOBIA.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines interact with RUKOBIA.

**Especially tell your healthcare provider** if you take birth control pills (oral contraceptives) that contain ethinyl estradiol. The amount of ethinyl estradiol can become increased in your blood during treatment with RUKOBIA. Talk to your healthcare provider about which oral contraceptives may be right for you during treatment with RUKOBIA.

Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with RUKOBIA.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take RUKOBIA with other medicines.

### POSSIBLE SIDE EFFECTS OF RUKOBIA

**RUKOBIA can cause serious side effects including:**

- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after you start taking RUKOBIA.
- **Heart rhythm problems (QTc prolongation).** RUKOBIA may cause a heart rhythm problem called QTc prolongation. QTc prolongation causes an irregular heartbeat. If you are elderly, you may be at a greater risk for developing this heart problem with RUKOBIA. **Tell your healthcare provider right away** if you feel dizzy, lightheaded, feel changes in your heartbeat, or you faint (lose consciousness).



## IMPORTANT FACTS (cont'd)

### POSSIBLE SIDE EFFECTS OF RUKOBIA (cont'd)

- **Changes in liver function blood tests results.** People with HIV-1 who take RUKOBIA and who also have hepatitis B or C virus infections, may be more likely to develop new or worsening changes in certain liver function blood tests during treatment with RUKOBIA.
  - If you stop your anti-hepatitis B treatment, this could mean that your hepatitis B may become active again (reactivated). Your healthcare provider may do blood tests to check your liver during treatment with RUKOBIA especially if you have hepatitis B virus infection.
  - Take any anti-hepatitis B or anti-hepatitis C medicines as prescribed by your healthcare provider during treatment with RUKOBIA.

- **The most common side effect of RUKOBIA is nausea.**

These are not all of the possible side effects of RUKOBIA.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

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### GET MORE INFORMATION

- Talk to your healthcare provider or pharmacist. Go to [RUKOBIA.com](http://RUKOBIA.com) or call 1-877-844-8872, where you can also get FDA-approved labeling. July 2020 RKB:1PIL Trademarks are owned by or licensed to the ViiV Healthcare group of companies.

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Research Triangle Park, NC 27709





*You've Got This*

Visit [RUKOBIA.com](https://www.RUKOBIA.com) to learn more

**ViiV**Connect

Check out ways to access your prescribed ViiV Healthcare medications

| Insurance Review

| Financial Assistance Programs<sup>a</sup>

**Call to speak to an Access Coordinator**

**Get support from ViiVConnect**



**1-844-588-3288 (toll-free)**  
Monday-Friday, 8AM-11PM (ET)



[ViiVConnect.com](https://www.ViiVConnect.com)

<sup>a</sup>Subject to eligibility and program terms and conditions;  
ViiVConnect programs do not constitute health insurance.

Please see Important Safety Information for RUKOBIA throughout this brochure and Important Facts about RUKOBIA on pages 9-10.



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