



fostemsavir (Rukobia)

WHAT IS FOSTEMSAVIR?

Fostemsavir, also known as fostemsavir tromethamine or FTR (brand name Rukobia), is a drug used as part of [antiretroviral therapy \(ART\)](#). The FDA approved fostemsavir in 2020 as an [antiretroviral drug \(ARV\)](#) for people with HIV infection. Fostemsavir is manufactured by [Viiv Healthcare](#).

Fostemsavir is first-in-class attachment inhibitor. Attachment inhibitors are a class of drugs that bind to the gp120 protein on the outer surface of HIV, preventing HIV from binding to and entering CD4 cells. Attachment inhibitors are part of a larger class of HIV drugs called [entry inhibitors](#), which include fusion inhibitors, CCR5 antagonists, attachment inhibitors, and post-attachment inhibitors. Entry inhibitors block HIV from entering host CD4 cells.

When used in combination with other ARVs to treat HIV infection, fostemsavir may help:

- Reduce the amount of HIV in your blood. This is called [viral load](#).
- Increase the number of [CD4 cells](#) in your blood that help fight off other infections.

Reducing the amount of HIV and increasing the CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting [opportunistic infections \(OIs\)](#) that can happen when your immune system is weak. [Read more about viral suppression](#).

Fostemsavir [does not cure](#) HIV infection or [AIDS](#). You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE FOSTEMSAVIR?

Fostemsavir is a prescription HIV medicine used in combination with other ARVs to treat HIV infection in adults who:

- have received several ART regimens in the past
AND
- have HIV that is resistant to many ARVs
AND
- are failing their current ART regimen (this could happen because the current ART is not working or no longer works, side effects are too severe, or there are other safety reasons)

The safety and effectiveness of fostemsavir has not been established in children under 18 years of age. Fostemsavir has not been carefully studied in the elderly (65 years of age and older).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your

healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. [Read more about U.S. ART guidelines.](#)

WHO SHOULD NOT TAKE FOSTEMSAVIR?

Do not take fostemsavir if you are allergic to fostemsavir or any of the ingredients in this drug.

Do not take fostemsavir if you are taking any of the following medicines. Taking fostemsavir with these medicines may affect how fostemsavir works. Fostemsavir may cause serious or life-threatening side effects or death when used with these medicines:

- [Cancer](#) medicines: enzalutamide, mitotane
- Seizure medicines: carbamazepine, phenytoin
- [Tuberculosis \(TB\)](#) medicines: rifampin
- Herbal product: St. John's Wort (*Hypericum perforatum*)

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with fostemsavir.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING FOSTEMSAVIR?

Before you take fostemsavir tell your healthcare provider about all of your medical conditions, and in particular 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 virus \(HBV\)](#) or [hepatitis C virus \(HCV\)](#) infection

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with fostemsavir. It is not known if fostemsavir will harm your unborn baby. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. [Read more about pregnancy and HIV.](#)

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with fostemsavir. It is not known if fostemsavir can pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one

ARV, it will also have resistance to other ARVs. This is called cross-resistance. [Read more about HIV drug resistance.](#)

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS FOSTEMSAVIR TAKEN?

Fostemsavir is taken by mouth as an extended-release tablet. The recommended dosage of fostemsavir for adults is 1,200 mg daily, taken as one 600 mg extended-release tablet twice daily.

Fostemsavir should be taken at the same time each day with or without food. Swallow fostemsavir tablets whole. Do not chew, crush, or split tablets.

You need to take fostemsavir in combination with other ARVs. Your healthcare provider will tell you what medicines to take and how to take them.

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary [side effects](#) such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of fostemsavir are nausea, [diarrhea](#), headaches, abdominal pain, indigestion, [fatigue](#), and rash.

Fostemsavir can cause serious side effects including:

Immune Reconstitution Inflammatory Syndrome (IRIS). [IRIS](#) is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting fostemsavir.

Heart rhythm problems (QTc prolongation). Fostemsavir 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 fostemsavir. Tell your healthcare provider right away if you feel dizzy, lightheaded, feel changes in your heartbeat, or you faint (lose consciousness).

Changes in liver functions blood tests results. People with HIV who take fostemsavir and who also have HBV or HCV infections may be more likely to develop new or worsening changes in certain liver function blood tests during treatment with fostemsavir. If you stop your HBV treatment, this could mean that your HBV may become active again (reactivated). Your healthcare provider may do [blood tests](#) to check your liver during treatment with fostemsavir, especially if you have HBV infection. Take any HBV or HCV medicines as prescribed by your healthcare provider during treatment with fostemsavir.

These are not all the possible side effects of fostemsavir. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects

to FDA at 1-800-FDA-1088.

HOW DOES FOSTEMSAVIR REACT WITH OTHER DRUGS?

All ARVs can [interact](#) with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take fostemsavir with other medicines.

See above for a list of medicines that should not be taken with fostemsavir.

If you take hormonal birth control pills containing ethynodiol diacetate and ethynodiol, the amount of ethynodiol can become increased in your blood during treatment with fostemsavir. Your birth control pill should not contain more than 30 mcg of ethynodiol per day. Talk to your healthcare provider about oral contraceptives that may be right for you during treatment with fostemsavir.

MORE INFORMATION

Visit the [Rukobia website](#).

Visit the [Rukobia healthcare professional website](#).

Download the full [Prescribing Information](#).

Download the [Patient Information](#) leaflet.

Download the [Rukobia Patient Brochure](#).

Check out the [ViiV Healthcare Patient Assistance Program](#).

Get a [ViiV Healthcare Savings Card](#).

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