

# elvitegravir (Vitekta)

#### WHAT IS ELVITEGRAVIR?

Elvitegravir (brand name Vitekta) is a drug used as part of <u>antiretroviral therapy (ART)</u>. The FDA approved elvitegravir in 2012 as an <u>antiretroviral drug (ARV)</u> for people with HIV infection. Elvitegravir is manufactured by <u>Gilead Sciences</u>.

Elvitegravir was sold from 2014 to 2016 as a single drug known as Vitekta. Vitekta was withdrawn from the market by Gilead Sciences in 2017, although elvitegravir is still available as a component of several combination HIV medicines (see below).

Elvitegravir is a type of drug called an <u>integrase inhibitor</u>. Integrase inhibitors block integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of host CD4 cells. Blocking integrase prevents HIV from replicating.

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

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of <u>CD4 cells</u> in your blood that help fight off other infections.

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

Elvitegravir <u>does not cure</u> HIV infection or <u>AIDS</u>. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

# WHO SHOULD TAKE ELVITEGRAVIR?

Elvitegravir is a prescription HIV medicine used in combination with other ARVS to treat HIV infection in adults who are already taking or have taken ARVs before.

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

All people living 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 ELVITEGRAVIR?

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

Do not take elvitegravir if you take any of the following medicines:

- Seizure medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicines: rifampin, rifapentine
- Hepatitis C virus (HCV) medicine: boceprevir
- Herbal product: St. John's Wort (*Hypericum perforatum*)
- Other ARV: <u>efavirenz (Sustiva)</u>
- Steroid medicine: dexamethasone (more than a single dose)

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 elvitegravir

#### WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING ELVITEGRAVIR?

Before you take elvitegravir tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have or have had liver problems, including hepatitis B virus (HBV) or HCV infection
- Take hormone-based contraceptives (birth control pills and patches)

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 elvitegravir. It is not known if elvitegravir may 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 elvitegravir. It is not known if elvitegravir 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.

#### to instructions, on schedule, and not to skip or reduce doses.

#### **HOW IS ELVITEGRAVIR TAKEN?**

Elvitegravir is available in two combination medications. Combination HIV medicines contain 2 or more HIV medicines from 1 or more drug classes.

- elvitegravir/cobicistat/emtricitabine/tenofovir AF (<u>Genvoya</u>)
- elvitegravir/cobicistat/emtricitabine/tenofovir DF (Stribild)

For more information about how these medicines are taken, click on the links above.

### WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary <u>side effects</u> 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 elvitegravir are diarrhea, nausea, and headaches.

Elvitegravir 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 elvitegravir.

These are not all the possible side effects of elvitegravir. 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 ELVITEGRAVIR REACT WITH OTHER DRUGS?**

All ARVs can <u>interact</u> 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 elvitegravir with other medicines.

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

If you use a hormonal birth control method containing norgestimate and/or ethinyl estradiol, the amount of hormone in your blood can be affected during treatment with elvitegravir. Talk to your healthcare provider about which contraceptives may be right for you during treatment with elvitegravir.

Antacids that contain magnesium or aluminum may interfere with the way that elvitegravir gets into your system. Elvitegravir should be taken 2 hours before or 6 hours after taking antacids.

## **MORE INFORMATION**

Visit the <u>Genvoya website</u>.

Visit the **Stribild website**.

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