

Patient Information
VITEKTA[®] (vye-TEK-tuh)
(elvitegravir)
tablets

Important: Ask your healthcare provider or pharmacist about medicines that should not be taken with VITEKTA. For more information, see the section **“What should I tell my healthcare provider before taking VITEKTA?”**

Read this Patient Information before you start taking VITEKTA and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

Also read the Patient Information for ritonavir (NORVIR[®]) and the other antiretroviral Human Immunodeficiency Virus-1 (HIV-1) medicines prescribed by your healthcare provider when taking VITEKTA.

What is VITEKTA?

VITEKTA is a type of prescription HIV-1 medicine that is used to treat HIV-1 in adults who are already taking or have taken HIV-1 medicines before. HIV-1 is the virus that causes Acquired Immunodeficiency Syndrome (AIDS).

VITEKTA must be taken with an HIV protease inhibitor medicine along with ritonavir (NORVIR[®]). You must also take other antiretroviral medicines prescribed by your healthcare provider.

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

When used with other HIV-1 medicines to treat HIV-1 infection, VITEKTA may:

- Reduce the amount of HIV-1 in your blood. This is called “viral load”.
- Increase the count of CD4+ (T) cells in your blood that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve the immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

VITEKTA does not cure HIV-1 infections or AIDS. You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others.

- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.

- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions about how to prevent passing HIV-1 to other people.

What should I tell my healthcare provider before taking VITEKTA?

Before you take VITEKTA, tell your healthcare provider if you:

- have liver problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if VITEKTA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking VITEKTA.

Pregnancy Registry. There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take VITEKTA.
 - 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 VITEKTA can pass to your baby in your breast milk.
 - Talk to your healthcare provider about the best way to feed your baby.

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

Do not take VITEKTA if you also take:

- cobicistat (TYBOST®) with a protease inhibitor
- other medicines that contain elvitegravir (STRIBILD®)

Especially tell your healthcare provider if you take:

- hormone-based contraceptives (birth control pills and patches)
- an antacid medicine. Take antacids at least 2 hours before or after you take VITEKTA.
- medicines used to treat seizures
- any of the following medicines:
 - boceprevir (VICTRELIS®)
 - bosentan (TRACLEER®)
 - buprenorphine/naloxone (BUNAVAIL™, SUBOXONE®, ZUBSOLV®)
 - didanosine (VIDEX®, VIDEX EC®)

- medicines that contain dexamethasone
- efavirenz (SUSTIVA[®])
- ketoconazole (EXTINA[®], NIZORAL[®], XOLEGEL[®])
- nevirapine (VIRAMUNE[®])
- rifabutin (MYCOBUTIN[®])
- rifampin (RIFADIN[®], RIFAMATE[®], RIFATER[®], RIMACTANE[®])
- rifapentine (PRIFTIN[®])
- St. John's wort (*Hypericum perforatum*) or products containing St. John's wort

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. Do not start any new medicines while you are taking VITEKTA without first talking with your healthcare provider or pharmacist.

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

How should I take VITEKTA?

- Take VITEKTA exactly as your healthcare provider tells you.
- VITEKTA must be taken with a protease inhibitor medicine which may include one of the following:
 - atazanavir (REYATAZ[®]) with ritonavir (NORVIR)
 - darunavir (PREZISTA[®]) with ritonavir (NORVIR)
 - fosamprenavir (LEXIVA[®]) with ritonavir (NORVIR)
 - lopinavir/ritonavir (KALETRA[®])
 - tipranavir (APTIVUS[®]) with ritonavir (NORVIR)
- Stay under the care of your healthcare provider during treatment with VITEKTA. See your healthcare provider regularly while you take VITEKTA.
- Do not change your dose or stop taking VITEKTA without first talking with your healthcare provider.
- Do not miss a dose of VITEKTA.
- Take VITEKTA 1 time each day.
- Take VITEKTA with food.
- If you take too much VITEKTA, call your healthcare provider or go to the nearest hospital emergency room right away.
- Do not run out of VITEKTA. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to VITEKTA and become harder to treat. When your supply starts to run low, get more from your healthcare provider or pharmacy.

What are the possible side effects of VITEKTA?

VITEKTA may 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 starting your HIV-1 medicine.

The most common side effect of VITEKTA is diarrhea.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of VITEKTA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VITEKTA?

- Store VITEKTA at room temperature below 86 °F (30 °C).
- Keep VITEKTA in its original container.
- Do not use VITEKTA if the seal over the bottle opening is broken or missing.

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

General information about VITEKTA

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VITEKTA for a condition for which it was not prescribed. Do not give VITEKTA to other people, even if they have the same symptoms you have. It may harm them.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about VITEKTA that is written for health professionals.

For more information, call 1-800-445-3235 or go to www.GILEAD.com.

What are the ingredients in VITEKTA?

Active ingredient: elvitegravir

Inactive ingredients: microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, lactose monohydrate, hydroxypropyl cellulose, and magnesium stearate. The tablets are film-coated and contain polyvinyl alcohol, polyethylene glycol, titanium dioxide, talc, indigo carmine, FD&C Blue #2 aluminum lake, and iron oxide yellow.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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