

Patient Information

GENVOYA[®] (jen-VOY-uh)
(elvitegravir, cobicistat, emtricitabine,
and tenofovir alafenamide)
tablets

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

Read this Patient Information before you start taking GENVOYA 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.

What is the most important information I should know about GENVOYA?

GENVOYA can cause serious side effects, including:

- 1. Build-up of lactic acid in your blood (lactic acidosis).** Lactic acidosis may happen in some people who take GENVOYA or similar medicines. Lactic acidosis is a serious medical emergency that can lead to death.
Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. Call your healthcare provider right away if you get any of the following symptoms which could be signs of lactic acidosis:
 - feel very weak or tired
 - have unusual (not normal) muscle pain
 - have trouble breathing
 - have stomach pain with nausea or vomiting
 - feel cold, especially in your arms and legs
 - feel dizzy or lightheaded
 - have a fast or irregular heartbeat
- 2. Severe liver problems.** Severe liver problems may happen in people who take GENVOYA. In some cases, these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis).

Call your healthcare provider right away if you get any of the following symptoms of liver problems:

- your skin or the white part of your eyes turns yellow (jaundice)
- dark “tea-colored” urine
- light-colored bowel movements (stools)
- loss of appetite
- nausea
- pain, aching, or tenderness in the right side of your stomach area

You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking GENVOYA or a similar medicine for a long time.

- 3. Worsening of Hepatitis B infection.** GENVOYA is not for use to treat chronic hepatitis B virus (HBV) infection. If you have hepatitis B virus (HBV) infection and take GENVOYA, your HBV may get worse (flare-up) if you stop taking GENVOYA. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.
 - Do not run out of GENVOYA. Refill your prescription or talk to your healthcare provider before your GENVOYA is all gone.
 - Do not stop taking GENVOYA without first talking to your healthcare provider.
 - If you stop taking GENVOYA, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking GENVOYA.

For more information about side effects, see the section “What are the possible side effects of GENVOYA?”

What is GENVOYA?

GENVOYA is a prescription medicine that is used without other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) in people 12 years of age and older:

- who have not received anti-HIV-1 medicines in the past, **or**
- to replace their current anti-HIV-1 medicines for people whose healthcare provider determines that they meet certain requirements.

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

GENVOYA contains the prescription medicines elvitegravir (VITEKTA[®]), cobicistat (TYBOST[®]), emtricitabine (EMTRIVA[®]) and tenofovir alafenamide.

It is not known if GENVOYA is safe and effective in children under 12 years of age or who weigh less than 77 lbs.

Who should not take GENVOYA?

Do not take GENVOYA if you also take a medicine that contains:

- alfuzosin hydrochloride (UROXATRAL[®])
- carbamazepine (CARBATROL[®], EPITOL[®], EQUETRO[®], TEGRETOL[®], TEGRETOL-XR[®], TERIL[®])
- cisapride (PROPULSID[®], PROPULSID QUICKSOLV[®])
- ergot-containing medicines, including:
 - dihydroergotamine mesylate (D.H.E. 45[®], MIGRANAL[®])
 - ergotamine tartrate (CAFERGOT[®], MIGERGOT[®], ERGOSTAT[®], MEDIHALER ERGOTAMINE[®], WIGRAINE[®], WIGRETTES[®])
 - methylergonovine maleate (ERGOTRATE[®], METHERGINE[®])
- lovastatin (ADVICOR[®], ALTOPREV[®], MEVACOR[®])
- lurasidone (LATUDA[®])
- midazolam, when taken by mouth
- phenobarbital (LUMINAL[®])
- phenytoin (DILANTIN[®], PHENYTEK[®])
- pimozide (ORAP[®])
- rifampin (RIFADIN[®], RIFAMATE[®], RIFATER[®], RIMACTANE[®])
- sildenafil (REVATIO[®]), when used for treating the lung problem, pulmonary arterial hypertension (PAH)
- simvastatin (SIMCOR[®], VYTORIN[®], ZOCOR[®])
- triazolam (HALCION[®])
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort

What should I tell my healthcare provider before taking GENVOYA?

Before taking GENVOYA, tell your healthcare provider if you:

- have liver problems, including hepatitis B infection
- have kidney problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if GENVOYA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking GENVOYA.

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 GENVOYA.
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - At least one of the medicines in GENVOYA can pass to your baby in your breast milk. It is not known if the other medicines in GENVOYA can pass into your breast milk.

Talk with 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.

Some medicines may interact with GENVOYA. 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 GENVOYA.
- **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take GENVOYA with other medicines.

How should I take GENVOYA?

- Take GENVOYA exactly as your healthcare provider tells you to take it. GENVOYA is taken by itself (not with other HIV-1 medicines) to treat HIV-1 infection.
- Take GENVOYA 1 time each day.
- Take GENVOYA with food.
- Do not change your dose or stop taking GENVOYA without first talking with your healthcare provider. Stay under a healthcare provider's care when taking GENVOYA.
- If you need to take a medicine for indigestion (antacid) that contains aluminum hydroxide, magnesium hydroxide, or calcium carbonate during treatment with GENVOYA, take it at least 2 hours before or after you take GENVOYA.
- Do not miss a dose of GENVOYA.
- If you take too much GENVOYA, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your GENVOYA supply starts to run low, get more from your healthcare provider or pharmacy. 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 GENVOYA and become harder to treat.

What are the possible side effects of GENVOYA?

GENVOYA may cause serious side effects, including:

- See “What is the most important information I should know about GENVOYA?”
- **Changes in body fat can happen in people who take HIV-1 medicine.** These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **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 any new symptoms after starting your HIV-1 medicine.
- **New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with GENVOYA. Your healthcare provider may tell you to stop taking GENVOYA if you develop new or worse kidney problems.

The most common side effect of GENVOYA is nausea.

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 GENVOYA. 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 GENVOYA?

- Store GENVOYA below 86 °F (30 °C).
- Keep GENVOYA in its original container.
- Keep the container tightly closed.

Keep GENVOYA and all medicines out of reach of children.

General information about the safe and effective use of GENVOYA.

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

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

What are the ingredients in GENVOYA?

Active ingredients: elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide

Inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, silicon dioxide, and sodium lauryl sulfate. The tablets are film-coated with a coating material containing FD&C Blue No. 2/indigo carmine aluminum lake, iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Manufactured and distributed by: Gilead Sciences, Inc. Foster City, CA 94404

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

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